EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC, REPAIR SYSTEM PRODUCTS, LIABILITY LITIGATION) MASTER FILE NO. 2:12-MD-02327 MDL NO. 2327

THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN wave 1 of 200:
MARIE BANKS, ET AL. V. ETHICON, INC., ET AL NO. 2:12-CV-01318
ROBIN BRIDGES V. ETHICON, INC., ET AL. NO. 2:12-CV-00651
DENNIS W. DIXON, ET AL. V. ETHICON, INC., ET AL. NO. 2:12-CV-01081
PAULA FISK V. ETHICON, INC., ET AL. NO. 2:12-CV-00848
SHERRY FOX, ET AL. V. ETHICON, INC., ET AL. NO. 2:12-CV-00878
LOUISE GRABOWSKI V. ETHICON, INC., ET AL. NO. 2:12-CV-00683
NANCY HOOPER, ET AL. V. ETHICON, INC., ET AL. NO. 2:12-CV-00493
WILMA JOHNSON V. ETHICON, INC., ET AL. NO. 2:11-CV-00809
LAURA WAYNICK, ET AL. V. ETHICON, INC., ET AL. NO. 2:12-CV-01151

JOSEPH R. GOODWIN
US DISTRICT JUDGE

APRIL 30, 2016

VIDEOTAPED DEPOSITION OF
DIONYSIOS K. VERONIKIS, M.D.

VIRGINIA WHITE, ET AL. V.)
ETHICON, INC., ET AL.)
NO. 2:12-CV-00958)
)
JULIE WROBLE, ET AL. V.)
ETHICON, INC., ET AL.)
NO. 2:12-CV-00883)

SATURDAY, APRIL 30, 2016

- - -

Videotaped deposition of Dionysios K. Veronikis, M.D., held at the Hilton St. Louis - Frontenac, 1335 South Lindbergh Boulevard, Frontenac, Missouri, commencing at 8:55 a.m., on the above date, before Carrie A. Campbell, Registered Merit Reporter, Certified Realtime Reporter, Illinois, California and Texas Certified Shorthand Reporter, and Missouri Certified Court Reporter.

- - -

INDEX

EXHIBITS

A P P E A R A N C E S :

BLASINGAME BURCH GARRARD ASHLEY, PC
BY: JAMES B. MATTHEWS, ESQUIRE
jbm@bbgbalaw.com
440 College Avenue
Athens, Georgia 30601
(706) 354-4000

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
BY: MARY LIU, ESQUIRE
mliu@awkolaw.com
17 East Main Street, Suite 200
Pensacola, Florida 32502
(850) 202-1010
Counsel for Plaintiffs

BRYAN CAVE, LLP
BY: DAN H. BALL, ESQUIRE
dhball@bryancave.com
JAMES P. EMANUEL, JR., ESQUIRE
James.Emanuel@bryancave.com
211 North Broadway, Suite 3600
St. Louis, Missouri 63102
(314) 259-2000
Counsel for Defendants

ALSO PRESENT VIA TELEPHONE:
Mark Mueller, Mueller Law Office

- - -

DIONYSIOS K. VERONIKIS, M.D.,
of lawful age, having been first duly sworn to tell the truth, the whole truth and nothing but the truth, deposes and says on behalf of the Defendants, as follows:

DIRECT EXAMINATION

QUESTIONS BY MR. BALL:

Q. Would you tell us your name, please?

A. Dionysios Veronikis, D-i-o-n-y-s-i-o-s, V-e-r-o-n-i-k-i-s.

Q. Dr. Veronikis, my name is Dan Ball, and I represent Ethicon. And I'm going to be asking you some questions about the two reports you've submitted in the federal court litigation involving TVT® and involving Gynemesh® PS.

You understand that?

A. Yes.

(Veronikis Exhibit 1 marked for identification.)

QUESTIONS BY MR. BALL:

Q. So the first thing I'm going to

do is mark as Exhibit 1 to your deposition and ask you to just briefly take a look at that.

A. Yes.

Q. Exhibit 1 is the notice to take this deposition, right?

A. Yes.

Q. And have you seen this before?

A. Yes, sir. It was e-mailed to me by Mr. Matthews.

Q. And there's an attachment to that asking you to bring various things to the deposition.

Did you get a chance to look at that.

A. I did, and I spoke with Mr. Matthews, and he said he would bring everything.

Q. Now, so do you have anything, I guess, Mr. Matthews to produce with respect to the depo notice?

MR. MATTHEWS: You want to -- well, those boxes there contain the documents that are referenced as

footnotes in his reports in both of them. This thumb drive contains everything that he was sent and reviewed.

MR. BALL: Okay.

MR. MATTHEWS: There's -- if you don't want to take the boxes or mark them as exhibits, there's a -- everything in those boxes is on a CD that I also brought with me.

MR. BALL: So I think what I'll do is mark the thumb drive and the -- or I don't even need to mark them. We can just -- yeah, I'll mark them. Mark them and that is the two CDs, I think it would be the most convenient way.

(Veronikis Exhibits 4 and 5 marked for identification.)

MR. BALL: Exhibit 4 is a thumb drive which is?

MR. MATTHEWS: All of his reference materials.

MR. BALL: And Exhibit 5 is a

CD which is?

MR. MATTHEWS: His reports for each product and the footnotes for each product. The documents that reference -- that are referenced in the footnotes.

MR. BALL: Great. Thank you for that.

QUESTIONS BY MR. BALL:

Q. Now, have you charged for your services in this case?

A. Not yet.

Q. Okay. Do you intend to?

A. Yes.

Q. Okay. And what will be the basis for your charges?

How will those be calculated?

A. It's an hourly rate.

Q. And what is that?

A. It's a thousand dollars an hour.

Q. And do you have an estimate as to how many hours you spent coming into the start of this deposition?

A. Could you -- just for preparation of this deposition?

Q. Yeah, that's fair. I'm going to ask a series of them so we'll start off.

First of all, to prepare the two reports that we're going to be talking about here today?

A. So it's about 50 hours.

Q. And any other work you've done in preparation for this deposition?

A. I reviewed everything that they had sent me, and it was a ton of stuff.

Q. And about how many hours was that?

A. 300. 350. I didn't add up the numbers just yet.

Q. Okay. So in connection with this deposition and these reports, you would estimate that you've spent in the neighborhood of 350 to 400 hours?

A. Yes.

Q. And what is your charge for deposition?

A. It's 6,000 for half a day,

10,000 for entire day.

Q. How about two-thirds of a day, what is that?

Is it done on some hourly basis or --

A. If it's an hour and a half or two hours sometimes, I'll, just to be fair, that's what it is. If it takes a half day or a full day, I try to be fair and consistent.

Q. And is that what your charge would be if you ever appeared for trial would be $10,000 a day?

A. Yes.

Q. Does that include -- if you had to travel to West Virginia, would it be $10,000 the day you travel over there?

A. It would be traveling expenses and my day there.

Q. So let's say you were going to testify on a Tuesday and you went over on a Monday, would it be $10,000 for Monday and 10,000 for Tuesday?

A. No.

Q. What would the Monday be?

A. My travel expenses.

Q. Okay. You wouldn't charge for your time in traveling?

A. No.

Q. Okay. Now, you also served as an expert witness on individual cases?

A. Yes.

Q. How many of those involving Ethicon?

A. In the patients I examined for everyone who sent or just Mr. Matthews?

Q. Everyone.

A. Maybe ten.

Q. Ten patients?

A. Yes.

Q. Okay. And do you have an estimate as to what your average billings were per case on each one of those?

A. It depends on the number of records and the time. It varies from 7, 8,000, depending on the records, to 12, 14.

Q. So 10 to 12 would be a good estimate on average?

A. Yes.

Now, on this notice --

Q. Yeah.

A. -- there's only one patient that I've seen from this notice.

Q. And I wasn't just limiting to that notice.

A. Okay.

Q. I was saying in general you've seen about ten patients, Ethicon litigation patients?

A. Yes.

Q. And they've been about 10 or $12,000 per patient to do an examination and a report?

A. Yes.

Q. And review the records?

A. Yes.

Q. And then in those cases, you either have or in the process of giving depositions on those?

A. I've been deposed on one patient.

Q. Okay. And that's a $6,000 per half day charge for that?

A. That was only two hours so I'll probably just submit for two hours. I think the Attorney Emanuel was there for that.

Q. So that would be a couple thousand dollars?

A. Right.

Q. Okay. Now, aside from the two reports that we're going to talk about here today and the ten patients that you've seen approximately, have you done any other work related to litigation involving Ethicon?

A. No.

Q. Okay. Now, have you been retained by a plaintiff to testify in cases against any other mesh manufacturers?

A. No.

Q. Have you ever been engaged to testify by a mesh manufacturer or serve as an expert by a mesh manufacturer?

A. No.

(Veronikis Exhibits 2 and 3 marked for identification.)

QUESTIONS BY MR. BALL:

Q. Exhibit 2 is a copy of the

report and materials that accompany the report relating to TVT® in this litigation; is that right?

A. Yes.

Q. And Exhibit 3 is a copy of the report and materials that accompanied the report in this litigation related to Gynemesh® PS; is that right?

A. Yes.

Q. Now, pursuant to the court rules, do Exhibits 2 and 3 contain all of your opinions and bases for those opinions that you intend to express in this litigation?

A. Up to this point, yes.

MR. MATTHEWS: So we're on the same page, some people have been doing depositions when the deponent has given two reports by doing the deposition on one report and then a separate deposition on the second report. Some people have just taken five hours to do kind of a combination.

MR. BALL: I thought it was six.

MR. MATTHEWS: It's five on the first, two on the second.

MS. LIU: Three on the first.

MR. MATTHEWS: I mean, three on the first, two on the second.

MR. BALL: I was told three and three because there's two -- calm down.

MR. MATTHEWS: It's three and two. And I don't care if you do five hours and combine them.

MR. BALL: I'm going to do five hours and combine them because I'm not good enough to draw that line so precisely.

MR. MATTHEWS: Fine with me.

MR. BALL: Having said that, I will try to kind of go through mostly TVT® stuff and then mostly Gynemesh® PS stuff.

MR. MATTHEWS: Doesn't matter as long as I know what game we're

playing.

MR. BALL: James, can you just send the few people, whoever you wish -- and I'm not questioning, I'm just saying I got different information -- and I just want to see what they said and see --

MR. MATTHEWS: It was an agreement between Tom Cartmell and Brian Aylstock and Dave Thomas. And that's the way every deposition has been done so far.

MR. BALL: I'm not disputing. I just want to --

MR. MATTHEWS: I understand. That's fine.

MR. BALL: -- trust and verify.

MR. MATTHEWS: I'm just trying to get out of here earlier.

QUESTIONS BY MR. BALL:

Q. All right. Now, what I would like to do, first of all, is talk about what your practice is and has been the last several years.

All right?

A. Sure.

Q. Do you perform surgery for stress urinary incontinence?

A. Yes, sir.

Q. Okay. SUI?

A. Yes.

Q. Okay. Do you perform surgery for prolapse?

A. Yes.

Q. Anterior, posterior, apical?

A. Yes.

Q. And of those two types of surgeries, which do you do more?

A. It's hard to say. You get patients that present with predominantly prolapse symptoms and when you reduce that prolapse, they also have incontinence. You have other patients that present with a primary complaint of incontinence, you examine them and they have other defects.

So you end up doing a lot. It might be fair to say, I don't know, 50/50.

Q. Okay. Do you also do surgery

to deal with issues related to mesh products that have already been implanted?

A. Unfortunately.

Q. Okay. How does that fall -- which is more common, that surgery or the original surgeries that you do for prolapse or SUI?

A. So I've limited the patients that I see with mesh complications and I try to balance that between 50 percent mesh complications and 50 percent primary patients.

Q. Has that been the case for the past several years, or have the percentages differed?

A. I've actually dialed it down a little bit.

Q. Dialed what down?

A. The number of patients that I will see with mesh complications.

Q. Okay. What did it use to be percentagewise?

A. Oh, at one point it was 60, 70 percent, and I'm in a training program and

by doing more of the complicated mesh removals, the residents in training weren't getting enough of the educational-type of procedures that they need to participate in. It created some grief so I dialed it back a little bit.

Q. And how long ago was it that it was 60 to 70 percent?

A. 18 months ago.

Q. So what is the -- what does that work out to annually if it's 50 percent, let's say, how many mesh complication surgeries per year?

A. So in 2015, I removed 296 implants. I did a total of 605 surgeries.

Q. Very precise.

The mesh implants that you removed, let's use last year, how many of those were for SUI as opposed to for prolapse?

A. I have that number, but I don't have it off the top of my head. I looked at some different numbers in preparation for this, but I would say that the vast majority

are for SUI.

Q. Vast majority of the removals?

A. Yes.

Q. Okay. Now, one of the products that we're going to be talking about here today is a TVT® device, true?

A. Yes.

Q. Made by Ethicon, true?

A. Yes.

Q. And have you ever implanted a TVT®?

A. I think I did it once or twice.

Q. Okay. When?

A. When it first came out.

Q. Do you have a specific recollection of that or not?

A. I have a specific recollection because Hattie Loggie, who was the local rep, was very interested in obtaining my business since I do a large volume and that would be good for her.

I know there were discussions after that they kept trying to get me to use it, but I was not happy with the approach to

implant the product or the product itself. So I kind of got pressured to try one because they said try one, and then I tried a second one, and I didn't do anymore.

Q. And when was that?

A. Early when it first came out, very early. Ballpark, 2000 to 2003.

Q. That time period?

A. Yes, sir.

Q. What was it about the approach -- you said the approach and the product, I think that's the word you used?

A. Yes.

Q. What was it about that --

A. Well --

Q. -- that you were dissatisfied with?

A. Yes. I was very used to doing synthetic slings, and being trained as a vaginal surgeon, I had ideas of what a safe, effective surgery should be. When I looked at the IFU and the videos for performing the surgery, it was apparent that the way that they wanted me to do it wasn't, in my

opinion, safe.

In the ones I did perform, I did not follow Ethicon's recommendations. I did what I normally do for slings and used their product.

Q. What was it about the procedure that you considered to be unsafe?

A. The procedure was supposed to start with a 1.5 centimeter incision, 1 centimeter from the urethra medias. That area of the anatomy immunologically develops from the sinovaginal bulbs, and it's fused so you can't really gauge the depth of dissection accurately. And it's a curvilinear structure. It's a tube. So you really need to separate that structure much more precisely.

So the way that the instructions were was to make an incision and then make a half-centimeter blunt dissection, and at the time they had the 5-millimeter trocar, and you're trying to take a round structure, a trocar, and compress it between the flap that you created and then they had

the device inside, the guide wire, which really doesn't do anything if you really think about it -- but I don't want to get ahead of myself.

So it was a 5-millimeter trocar, supposed to make a 5-millimeter incision and tunnel it a little bit. I had read Ulmsten's original report and in his original report you were supposed -- he said make .5 to 1 centimeter. So the difficulty I had was with the pressure that was required to pass the trocar, the snug fit between the vaginal wall and the urethra, which was a tubular structure, not moving the lateral bladder side wall. The guide wire would be like taking a pen and putting it into a water bottle; it's not going to move the sides in. And the safety aspects of doing a sling is to move the paravaginal retropubic space and open that up and move the bladder medially so when you pass that trocar, you're literally passing it through an open space.

The technique that was described and asked me to do I thought it was

unsafe. It yielded a high risk of a bladder puncture and injury. So I didn't follow those.

Q. Did you use the -- the procedure you did use, did you use the trocar that came with the sling?

A. I used the trocar, but I didn't use the handle.

Q. Okay. And just briefly how did your approach differ from what was recommended in the IFU?

A. Sure.

So I started my incision about the midanterior vaginal wall. I identified the vesicovaginal space. What that had me do is it identified the blood supply and the thickness of the vaginal wall. I carry that dissection all the way to the urethra medias. I separated the vaginal wall from the urethra. I then pierced the urogenital diaphragm, created a much larger than 1-centimeter opening. I opened the retropubic space.

I developed an instrument that

allows me to get on the side of the bladder between the obturator internus muscles and the bladder sidewall and push that bladder wall over. Holding in that blunt retractor, sort of like a trocar but it's blunt, so when you push it, it won't poke a hole. I was able to move the bladder and all of the structures to the posterior aspect of the abdominal wall. Then touching that blunt retractor with a sharp trocar, the only thing I pierced was the rectus muscles. I did that on both sides.

Q. Which is what you wanted to pierce?

A. Yes.

Q. Okay. Now, the instrumentation and the procedure that was in the IFU and with the TVT® back 15 years or so ago when you did this, is that the same -- has that before changed?

Has Ethicon ever changed either for the TVT®, either its instrument or its recommended procedure?

A. I'm going to ask a question.

Q. Sure.

A. You're assuming we're talking about retropubic slings?

Q. Yes. That's all your report deals with.

A. Yes, I didn't comment on TVT® Exact, but they did --

Q. But your report is only about the TVT® retropubic sling?

A. Yes, sir.

Q. That's all I am talking about here. And if I ask about something else, I'll --

A. Okay. They did change it and call it TVT® Exact where they changed the trocar a little bit and put a plastic sheath on the end of the mesh, but the tenets of the procedure pretty much stayed the same.

Q. So the TVT® even through the TVT® Exact, both the instrument and the recommended technique have remained essentially the same?

A. They have.

And what it does is it takes a

1-centimeter mesh and upon implantation, it forces it to fold in that 5-millimeter tunnel.

Q. Do you have more criticism of the TVT® with respect to the procedure and the trocar instrumentation that's being used or with respect to the mesh itself?

A. I have criticisms of the entire kit, and that kit consists of the delivery system and the mesh.

Q. I know that.

What I asked you is do you have criticism more of one than the other, the technique and the instrumentation on the one hand versus the mesh?

A. I have criticism of both. I don't know which one would be more because they're sort of together. You really can't isolate the one from the other.

Q. Now, what do you use polypropylene slings today for SUI?

A. I do.

Q. Okay. What product?

A. I'm currently use Caldera. I

used to use BARD Uretex.

Q. So Caldera is a company?

A. Yes, sir.

Q. Does it have a brand within that company?

A. I think the implant is called Desara.

Q. And how long have you been using that?

A. Since 2010.

Q. Does that come with instrumentation?

A. Instrumentation is provided, yes.

Q. Do you use it?

A. I do not.

Q. And does it come with an IFU?

A. It does.

Q. Does the IFU give a recommended technique?

A. It does.

Q. Do you follow that technique?

A. I do not.

Q. Why do you not use the

instrumentation that comes with the Desara?

A. It's not designed quite right.

Q. Okay. Do you believe it is, at least to some degree, unsafe, use of that instrumentation?

A. I've never used it.

Q. Okay. And you don't use it because you think it might be unsafe?

A. I don't use it because I designed my own trocar that allows me more precision in how to handle it.

The TVT® trocar had a handle on it. I didn't use the handle, but at least that handle was detachable. The Desara handles have a nondetachable handle. It gives you too much torque. So I developed a trocar that does -- that limits how much torque you apply. Makes it safer.

Q. Is that your own special -- does it have a name?

A. No.

Q. Okay. Is it commercially available?

A. It can be but, no.

Q. What do you mean?

A. Well, if someone wanted it, I would make one for them.

Q. But you're not trying to commercially develop them?

A. Oh, no. No.

Q. Why don't you use the Desara technique?

A. All of the techniques are pretty much the same for all the slings. They all want you to do it kind of the same way.

Q. The way you described on the TVT®?

A. Yes, sir.

Q. Okay. And for the reasons you've described, you don't find that acceptable and you use the technique that you described earlier?

A. Yes.

Furthermore, the Desara product doesn't have a tubular attachment to it so it allows me to tailor the surgery to my own preferences as opposed to being confined.

It's not as easy to do that with some of the other slings.

Q. Including the TVT®?

A. Yes.

Q. You said you used a BARD product before the Desara?

A. Yes.

Q. And what was the name of that?

A. Uretex.

Q. And did that have an instrumentation to be used?

A. It did.

Q. Did you use it?

A. I did.

Q. Okay. Did you think it was good?

A. It was good.

Q. Okay. Why did you change from Uretex to Desara?

A. The company got sold. I couldn't get it anymore.

Q. And in terms of technique, was the technique recommended with the Uretex about the same as the TVT® and the Desara?

A. Yes.

Q. And you did not use that technique?

A. I did not.

Q. Okay. What was it about the Uretex instrument that made it acceptable to use and so you didn't use your own?

A. It allowed me to pass the trocar without the sling. So I was able to create my exposure, dissect the vaginal wall, open it the way I like, dissect the retropubic space, pass the trocar, leave -- at that point it was a little plastic tube -- leave a little blue tube in position, remove the trocar, do the other side, not bring the sling into the field at all because it is sort of a contaminated area.

So it allowed me to not bring the mesh on to the field until I was ready to implant it. Because if you have a bladder puncture, you had bleeding, the patient was stooling on the table, you know, you had complete control of it, which is what I'm able to do with Desara, which is what I did

for my first sling.

So the slings I have used have been an Ethicon Mersilene from '94 to 2003 --

Q. Did you think that was a safe product?

A. I did at the time.

Q. Do you today?

A. Its properties as an implant are questionable. It deteriorates.

Q. But --

A. So from then, the reason I changed was I wanted a less invasive sling.

When you used a completely home-crafted sling, you made incisions that were 5 centimeters on the each side. Almost looked like an hernia repair, more invasive, took more OR time.

Q. That was the Mersilene?

A. That was the Mersilene.

But it worked fine. Had a very high success rate. Steve Young did a paper on it with good outcomes, few complications, and then the trend was to do less invasive surgery. Data came out that polyethylene

terephthalate, which is what Mersilene was, may be degrading a little bit. I certainly didn't want that.

It was touted that polypropylene was the next great material. It was less invasive, and I developed a technique that was very similar to the Mersilene placement, which I was very comfortable with, which I knew what the outcomes were, and went to Uretex.

Q. Okay. So '94 to 2000 was Mersilene, and then 2000 to 2010 was Uretex, or did I miss anything in between?

A. Close.

So '94 to about 2003.

Q. Okay. Was Mersilene?

A. Mersilene.

I also didn't like the TVT®. I was kind of spoiled. When I handled the Mersilene, it didn't fray, it didn't fall apart. I could manipulate the edges. I could suture the edges. There was things that I could do to it that I still do surgically that I could not do with the TVT®.

One of the things with Mersilene is that it has a bias. So the first thing I did, knowing that, and I didn't know any better, was I pulled on the TVT® and it frayed.

Q. Is Mersilene still sold for sling repairs?

A. It was never really sold for sling repairs. It was sold as a product that you used as a surgeon as you saw fit.

Q. Okay. Did you have to cut it for a particular surgery?

A. Yes.

Q. Okay. Did it come with its own instruments?

A. It did not.

Q. Okay. So just so I've got the timeline.

'94 to 2003, the Mersilene product from Ethicon?

A. Yes.

Q. Which was called what, just called Mersilene?

A. Yeah, just -- well, there's two

Mersilenes to clarify. There's Mersilene mesh, which comes in a sheet which is about 10 inches by 10 inches, and there's Mersilene ribbon, which is used for cerclage, which is actually one of the first uses of a sling was by Tiffany Williams and TeLinde in '62. It was a very similar TVT®, small needles, and they used it for cerclage --

Q. Which did you use?

A. The Mersilene mesh.

Q. The sheet?

A. Yes, sir. And I would cut it, like you said.

Q. Okay. And then from '03 to '10, you used the BARD Uretex until it wasn't sold anymore, and then from '10 forward the Desara?

A. Yes.

Q. Now, do you know or have any opinion today as to -- what else is out there?

There's the TVT®?

A. Yes.

Q. And the various iterations of

the TVT®?

A. Yes.

Q. And then there's Desara?

A. That's Desara.

Q. What else?

A. There's Advantage and Advantage Fit by Boston Scientific.

Q. Okay.

A. There was a line by BARD. There is the Supris by Coloplast. And I'm not sure if I'm missing anyone.

Q. Have you used any of those other ones that you just mentioned, the Coloplast, the BARD Align or the Boston Scientific one?

A. I used the Align when -- because BARD was the import of Sofradim from France.

When they were no longer able to get it, they said they were coming out with a sling. I tried it. I did not like the characteristics. I confirmed that sling was -- didn't have the same characteristics as the Uretex. When I would operate at a

certain hospital, the only product they had was Boston Scientific so they would not get me the Desara. So on a few cases I had to use the Boston Scientific product.

Q. What hospital was that?

A. St. Anthony's.

Q. Okay.

A. I stopped going there because of that.

Q. Okay. Did you think that was an acceptable product or not?

A. Very heavy. It had the same limitations as the TVT® Exact. It's a flat, 1-centimeter piece of mesh rolled and attached to almost like a straw where you put the trocar through there.

Again, I didn't follow the manufacturer's instructions.

Q. All right. Now, of those that have been on the market the last several years, do you have any opinion or impression as to which has been most commonly used by surgeons for SUI?

A. I don't.

Q. So you don't know which one is the biggest seller, so to speak?

A. No, but I see how many of each I remove, and it's -- the TVT® is maybe a little bit higher because the brand name was really smart marketing, TVT®. It was the first on the market so it had a large market share. So probably the TVT® is a little more popular maybe.

Q. Have you ever had to remove a BARD -- I've already forgotten the name.

A. Align.

Q. No the one before that?

A. Uretex?

Q. Yes.

Have you ever had to remove a BARD Uretex?

A. Yes.

Q. Several?

A. Yes.

Q. Have you ever had to remove a Desara?

A. I removed a Desara TOT. I have not removed the Desara retropubic.

Q. And have you ever had to remove all or a portion of a sling implanted by you?

A. I release slings for some voiding difficulty. I cut them in the middle.

Q. Have you ever had to remove a sling or a portion of a sling?

A. I've reviewed --

Q. Implanted by you?

A. Yes, I've removed a sling I've implanted.

Q. How many?

A. To my knowledge, one.

Now, that was a lady that had a previous TVT®, had a failure. I got a sling, a second sling, and was still having incontinence. So what I did is I removed both the TVT® and my sling to start over.

Q. Is it your testimony that the TVT® procedure kit, product, is so unsafe that it never should be on the market?

A. I think the risks far outweigh the benefits.

Q. So it never should have been

sold?

A. No.

Q. You agree with that?

A. I agree with that.

Q. Okay. Do you know anybody else in the world who agrees with that opinion that the TVT® never should have been sold?

A. I don't know a lot of people so I'm really -- I really shouldn't -- can't answer that.

Q. Well, the answer is you don't know anyone that shares that opinion, true?

A. I think a more appropriate answer is I don't really talk about this stuff with other people too much about what their preferences are.

Q. Is there any piece of literature or study, any piece of medical or scientific literature that you can point to that supports your opinion that the TVT® risks so outweigh its benefits that it never should have been on the market?

A. It says that exact statement?

Q. Or that supports that

statement.

A. I think there's papers that state that there's degradation of the mesh and there is a paper that says that the complications are not what's really reported in the literature. So some of the complications that were seen are skewed in a very specific way.

Q. Okay. Which paper is that?

A. I think her name was Anger.

Q. And what's the paper that says there's degradation?

A. That would be Clavé.

Q. Was that in vivo degradation that was reported by Clavé?

A. Yes.

Q. So back to my original question because that wasn't quite -- I appreciate that information, but that wasn't quite the answer.

Is there any paper you can point to that you believe reaches the conclusion -- I'll change it a little bit -- that reaches the conclusion that the risks of

TVT® outweigh the benefits so that it never should have been sold?

A. I don't think that a lot of surgeons have the viewpoint that I have because they're not seeing these women with all these complications. Even I have not reported all my complications. Not my complications, the patients that present.

So until that paper is written, I don't think that there's anyone that's going to support that view just yet.

Q. So the answer to my question is you're not able to point to any study or any literature or any paper that expresses the opinion that you have that the risks of TVT® outweigh the benefits so that it never should have been sold?

A. No paper that I know of.

Q. Now, how many TVT®s have you removed?

A. I can tell you what it was in 2015. 34 retropubic.

Q. Okay. Do you have any estimate as to how many you've removed in your career?

A. Several hundred.

Q. Okay. Which has been studied more long term, the TVT® or the Desara sling?

A. TVT®.

Q. Are you familiar with the Nilsson 17-year study on the TVT®?

A. I think I am.

Q. Okay. Is that referenced in your report anywhere on TVT®?

A. I don't think so.

Q. You're aware of a -- it's a 17 -- it's a study that followed women for up to 17 years with the TVT® and reported results.

You know which study I'm talking about or not?

A. I do.

Q. Okay.

A. I think there was two of them. I was hesitating for a second because I think there's a 2008 paper and there's one that came a few years after that. I think you're referring to the 2017 paper -- or is it 2017 paper -- no, 17 years.

Q. We're not into 2017 so it can't be a 2017 paper.

A. No, I do recall reading the paper.

Q. Can you tell me why that paper is not referenced in your report?

Let me back up. Let me withdraw the question and ask this.

In your report, Exhibit 2, about the TVT®, did you attempt to get a fair and balanced assessment of the issues related to the TVT®?

A. I did.

Q. Okay. Did you in the report reference any literature that would be contrary to your opinion that the risks of the TVT® outweigh the benefits?

Did you reference any papers like that in your report?

A. I did.

Q. Okay. And did you reference all of the papers in your report that would be contrary to that opinion?

MR. MATTHEWS: Well, I

didn't -- object to the form of the question.

THE WITNESS: There are so many papers on TVT®, it's not possible to reference all the papers.

QUESTIONS BY MR. BALL:

Q. Okay. Why did you not reference the Nilsson 17-year study paper?

A. I have a little problem with that paper. That paper started with 90 patients, if I remember the one that's correct, and by the time they followed those patients, half -- they only followed half, which was 45 patients. That's not an adequate sample of a longitudinal study.

Q. Which paper referenced in your report do you believe does not support your conclusion that the risks of TVT® outweigh the benefits?

A. That would be the Thomas study, trial of midurethral sling.

Q. What does it say?

A. They compared retropubic sling to TOT to see if they both kind of were

equal. Partially because there's so many retropubic injuries and traumas from passage of those trocars, which, in my opinion, is related to the technique, and that report shows that at one year it seems like both slings are pretty equal. That's a good paper.

The problem with the paper is it's only one year. It really didn't look at all the issues that occur years later. Most of these women that I'm seeing in my practice aren't showing up a year after a sling. They're showing up five, six, seven, eight, nine years later, and some of these problems have persisted for years.

Q. The Thomas paper did not address the risk versus benefits of just the TVT®, did it?

It was a comparison between the TVT® and the TVT-O?

A. TVT®, TVT-O and Monarc.

Q. Is there anywhere in Exhibit 2 where you expressed criticism of the technique or instrumentation with respect to

the TVT®?

A. There is.

Q. Would you show me where that is?

A. Sure.

It's on page 9. It starts on page 9.

It says the force required to implant the TVT® with the metal introducers deforms the mesh and the mesh can also deform after implantation. The design of the TVT® trocar, size, arc, handle with the TVT® mesh is a design mismatch for the pelvis --

Q. I understand.

I didn't get that one. Now with your explanation earlier, I understand what you're saying there.

A. Okay.

Q. So I appreciate that.

A. Okay.

Q. Do you believe that most doctors that -- well, strike that.

The TVT® has been used millions of times in surgery over the years, true?

A. I don't -- I'm sure. I don't know the exact number. I'll take your word for it.

Q. You wouldn't disagree with that?

A. No.

Q. And the great majority of those times that it has been used, it's been successful?

A. I don't know what the overall success rate in those millions is.

Q. The great majority of the time that the TVT® has been used in surgery, it's been used with the instrumentation and the technique recommended by Ethicon, true?

A. I don't know anyone else that's using the technique that I'm using.

Q. Okay.

A. Except my partner. I am sorry.

Q. You don't know anyone else that's using any different technique than what's recommended by the --

A. No. As I mentioned earlier, it's not something that I discuss with folks

a lot.

Q. Do you have an opinion as to what the success rate is with the -- if done by a surgeon using the technique and instrumentation recommended by the manufacturer, do you have an opinion as to what the success rate is with the TVT®?

A. I do.

Q. Okay. What is that opinion?

A. The original success rate by Ulmsten was basically 85 percent cure. It was sadly 11 percent improvement. But it's 85 percent cure, about 7 percent improvement, about 7, 8 percent didn't have an improvement. That was original data by Ulmsten.

The data by the Thomas trial was a little bit less.

Q. So what is your opinion with regard to the success rate of the TVT®, if you have an opinion?

Based upon review of the literature, your own knowledge, do you have an opinion as to what the success rate is

with the TVT®?

A. So my --

MR. MATTHEWS: Hold on. Object to the form because I don't know what you mean by the definition of "success rate."

QUESTIONS BY MR. BALL:

Q. Okay. Go ahead.

A. I read the papers, and I see numbers from 40 to 90. So my opinion is based on the success rate of those individual groups of patients that are reported. I have a very biased view because I see patients that have failure with leaking. And if you're only measuring the success rate, not leaking, it's about what those papers report.

Q. Okay. So let me make sure. So your opinion would be that the success rate with TVT® is approximately 85 percent cure and about 7 percent improvement, and about 7 or 8 percent no improvement?

A. That's right. For the treatment of the leaking part.

Q. Okay. I think that's going to

lead to my next question.

Do you have an opinion -- see if this was what you were getting ready to add.

Do you have an opinion as to the percentage of complications? Is that what you're going to be talking about, or no?

A. No.

Q. What do you mean when you said for the percentage of the leaking part?

A. That's what 85 percent success refers to, which is the testing they did afterwards on pad testing and cough stress test. That's how they measured the success.

Q. So if it stopped completely, that was a cure?

A. Yes.

Q. And if it improved it, that was an improvement?

A. Correct.

Q. All right. I'm with you.

Now, new question, do you have an opinion as to the complication rate -- and by that I don't mean temporary, I mean

long-term complication rate -- with TVT®?

A. I don't think that anyone can answer that question.

Q. Okay. So you don't have an opinion?

A. I have an opinion.

Q. Okay. Your opinion, I can't answer it?

A. Well, I can't give you a percentage. I guess what I was thinking, to be very transparent, give you a number like I gave you for the treatment of incontinence. I can't give you a number because I'm sure someone knows the denominator of how many slings went in, but -- or maybe the numerator, no one knows the other number of how many people are having problems. I know what problems I see, and I've not reported all these for any manufacturer.

I know other doctors are taking care of problems. But there hasn't been a national registry in the United States that looks at how many went in and what the problems are.

Q. Okay.

A. And until that happens, it's hard to estimate.

Q. Do you have -- do you tell your patients what the likelihood of complications is with -- in terms of percentages with an SUI procedure?

A. The way I do it and what I do, yes, I do.

Q. What do you say?

A. 2 percent retention rate.

Q. 2 percent will have a retention problem?

A. 2 percent will have a retention problem requiring an adjustment of the sling, not a removal.

Q. Okay. Can you tell me anything else about complication rates?

A. Bleeding.

Q. Can you give percentages on any of these?

A. It's very rare. I've not transfused a patient from an SUI procedure in years.

I talk about bladder injury because I get patients that have previous slings or previous other procedures.

Q. Now, I'm going to get into all of the possible complications here in a minute.

What I was asking is in terms of in your practice over the last 10 or 15 years, have you given patients any percentage? And you mentioned that you tell them there's a 2 percent urinary retention.

A. Incomplete bladder emptying retention.

Q. Any other percentages that you give them?

A. No.

Q. In terms of complications?

A. That's the only one, because all the other things with the technique I employ are exceedingly rare.

Q. Do you ever use non-mesh for SUI?

A. Yes, I do.

Q. How often?

Like if you take all of your SUI treatments in the last few years, what percentage has been non-mesh?

A. It's going up. It's about 15 percent now.

Q. 15?

A. 15.

Q. What methods do you use?

A. Either autologous fascia or cadaveric fascia.

Q. Autologous means what?

A. I remove a little bit of fascia from the patient's own body.

Q. Where do you remove it from?

A. Either the abdomen or the leg. It depends whether they have had hip replacement or if they've had multiple surgeries.

Q. And what do you do, fashion a sling out of that?

A. Yes. It's a basically a small little strip.

Q. And then cadaveric is the same?

A. Yes.

Q. It's a piece of tissue from another body?
A. Yes.
Q. That you fashion into a sling?
A. Yes.
Q. How is it -- or why is it that you use one of those two?
Do you use either one of those more than the other?
A. I give those options to the patient. Every patient with SUI now has a conversation regarding mesh and complications and what they've seen on the news and heard on the radio.
Q. Do you have to use sutures in connection with those autologous or cadaveric slings?
A. The approach I use is exactly the same whether I'm using synthetic, autologous or cadaver.
Q. Do you have to use sutures?
A. Yes.
Q. And those are polypropylene sutures?

A. No.
Q. What are they?
A. Polyglyconate suture. It's Vicryl Polysorb.
Q. They're absorbable?
A. Yes.
Q. This 15 percent, is this just patient's choice?
A. Yes.
Q. Or do you recommend one versus the other?
A. I give them the options.
Q. Okay. And so that 15 percent now these days are choosing the cadaveric?
A. Yes.
Q. Or the autologous?
Am I saying that right, autologous?
A. Yes.
Q. When did you start that?
A. I've always done autologous slings.
Q. No. I meant when did you start giving them, saying, "Here are the three

choices, what do you want to do?"

When did you start that?

A. The last few years. I can't remember exactly when.

Q. Okay. Other than any other type of -- you don't use the Burch procedure anymore?

A. If they ask, but typically I'm doing a lot of vaginal surgery and the Burch procedure would necessitate an incision. If I'm doing --

Q. An abdominal incision?

A. Yes. If I'm doing an abdominal approach, when I'm right there.

The reason I switched to a less invasive sling was not to make the abdominal incisions and et cetera.

Q. Right.

So you don't do very many Burches anymore?

A. I never really did.

Q. And how about MMK?

A. It's a variation of a Burch. I always preferred the Burch, but the MMK is an

option.

Q. How many of those do you think you've done in the last ten years?

A. Last ten years?

30, 40.

Q. And that was when you already had to have an abdominal incision anyway?

A. Yes.

Q. Okay. Is acute or chronic pain a risk of a non-mesh SUI surgery?

A. Acute pain can be.

Q. Not chronic pain?

A. Huh-uh.

Q. Is acute or chronic pain with intercourse a potential risk of non-mesh surgery?

A. No.

Q. So having pain with intercourse after an SUI surgery, non-mesh, is not a risk at all?

A. It's virtually unheard of.

Q. Is vaginal scarring a risk with non-mesh SUI surgery?

A. Typically, no.

Q. Is infection a risk with non-mesh SUI surgery?

A. You can get a hematoma and infection, yes.

Q. Is urinary frequency, urgency, dysuria, retention or obstruction or incontinence, are those risks of non-mesh SUI surgery?

A. Yes.

Q. Are UTIs as a result of retention a risk of non-mesh SUI surgery?

A. Yes.

Q. Is organ or nerve damage a risk of non-mesh SUI surgery?

A. Can be, yes.

Q. Okay. Is bleeding a risk with non-mesh SUI surgery?

A. Absolutely.

Q. Wound complications?

A. Sometimes.

Q. Inflammation?

A. Short-term inflammation.

Q. Fistula formation?

A. No.

Q. How about are neuromuscular problems in the pelvic floor muscles, the lower extremities or the abdominal area, are those risks of non-mesh SUI surgery?

A. I'm not sure I understand that last question.

Q. Okay. You don't know what a neuromuscular --

A. I do, but they were all kind of lumped together.

Q. Okay. Can you have -- let me unlump then.

Can you have neuromuscular problems in the pelvic floor muscles related to non-mesh SUI surgery?

A. You can.

Q. How about neuromuscular problems in the lower extremities?

A. Not related to the procedure, no.

Q. What about in the abdominal area?

A. If you're harvesting the tissue from there, yes.

Q. Okay. Is recurrent surgery a risk of non-mesh SUI surgery?

A. Yes.

Q. And is a foreign body response from sutures a risk of a non-mesh SUI surgery?

A. If you use a polypropylene suture.

Q. Okay. Are sometimes polypropylene -- is that an acceptable practice to use polypropylene sutures in non-mesh SUI surgery?

A. Some do.

Q. It's acceptable?

A. I don't know if it's acceptable; some do.

The tensile strength is different. Most will use a non-monofilament suture because if you touch it with the forceps or you tie it, it fractures and it breaks and it fails. So most of us that do different kinds of surgeries will use a non-monofilament polypropylene suture.

Q. And is that type of suture

subject to potential foreign body responses?

A. In the short term.

Q. That type of suture, can it have erosion or exposure?

A. Sometimes.

Q. In a non-mesh SUI surgery?

A. Yes.

Q. And is contraction of tissues a risk in a non-mesh SUI surgery?

A. No.

Q. Okay. Now, is there any risk related to the mesh that is present with the TVT® mesh that is not present with the Desara mesh?

A. Yes.

Q. Okay. What is that?

A. The Desara does not fray. It's a very stable weave.

Q. Okay. By fray, you mean what? On the edges?

A. On the edges. It doesn't deform when you pull on it.

Q. Okay. So have you ever seen evidence of fraying in any TVT® that caused

any clinical problem in your view?

A. Yes.

Q. Okay. Tell me about that.

A. So when I first started -- first of all, when it first became blue is when it really became apparent. You would open up the anterior vaginal wall, you would actually see little curly pieces of portions of mesh stuck to the inside of the vaginal wall.

Q. And what clinical issues were those causing?

A. I'm getting there.

Q. Okay.

A. I'm getting to that. So that was the first observation. So that came off of the implant.

So when you lose part of the weave, the mesh elongates and ropes and cords and twists and rolls, and as soon as it does that, it goes from being whatever its gram per meter squared weight is, it's immediately doubled.

And the additional part that is

very, very important is that the pores coalesce. So whatever the pores -- when it's sitting on the table before it's implanted, once it's implanted with any type of force on it, the pores -- the effective pore size becomes very small.

Q. Have you ever measured the effective pore size on a TVT®?

A. Personally, no.

Q. Okay. Are you aware of any study that has done that?

A. I've seen documentation inside the Ethicon documents that tells me what the pore size it.

Q. In vivo?

A. Not in vivo.

Q. Okay. So do you have an opinion as to what the effective pore size in vivo is in a TVT®?

A. I do.

Q. Okay. What is it?

A. It's less than before it got implanted.

Q. Do you have anything more

precise than that?

A. Sometimes there is no pores. It completely coalesces very easily. The stretchability of the mesh is desirable, but the problem with it is that it deforms so much that it -- there's virtually no pore. It's a tiny little slit.

Q. By the Amid classification is the mesh in TVT® a large pore mesh?

A. By the Amid classification, yes.

Q. In your view is it generally recognized that the TVT® is a large pore mesh?

A. Oh, by Ethicon's documentation is considered microporous.

Q. In the medical community, is it generally -- is the TVT® mesh generally regarded as a macroporous mesh?

A. Before it's implanted, yes.

Q. In the medical community, is the TVT® mesh generally regarded as lightweight?

A. No.

Q. Which is lighter weight, the Desara or the TVT®?

A. They're the same weight.

Q. Okay. Which has larger pores, the Desara or the -- what do you call it, the opposite of in vivo?

When it comes out of the box, which has larger pores, Desara or TVT®?

A. Desara.

Q. Do you know the dimensions of the Desara sling?

A. You mean the pore size?

Q. Yeah.

A. Yeah, it's approximately 1,200 microns.

Q. What is the size of the TVT® pores?

A. About a thousand microns.

Q. What is the size -- what was the size of the Uretex?

A. 1,160.

Q. Do you have an opinion as to what the pore size in the body is of the Desara or the Uretex?

A. I do.
Q. What is it?
A. It's greater than 1,160, greater than 1,200.
Q. They get bigger?
A. I make them bigger.
Q. Okay. How do you do that?
A. I am sorry, I was a little remiss. I didn't mention that when I place the sling in the midurethra, I sew it in a configuration -- I attach it with absorbable sutures in a configuration that opens the pores up more.
Q. Is that recommended in the IFUs for either Uretex or Desara?
A. No.
Q. So if you didn't do that technique, do you have an opinion as to what the effective pore size would be for the Desara or the Uretex?
A. I do not.
Q. It would be something less than they're designed?
A. You would think so.

Q. Okay.

A. And when I tried to do that with TVT®, I couldn't because of the edges fraying.

Q. Okay.

A. When I tried those two. But I always thought that the pores on all the slings that came after the Ethicon Mersilene were small because I was spoiled. I was used to seeing large pores where I could open the tissue up and if you held and just looked for a second, you could actually see the turgor pressure of the tissue coming through the pores before the operation was done. So having that visual confirmation and then not having it with polypropylene made me think.

Q. Did you think the pores, the preimplantation pore size, was larger in Mersilene?

A. It's definitely larger.

Q. What is it?

A. 23 -- 2.3 millimeters.

Q. 2,300?

A. Yes.

Q. Microns?

A. Yes.

Q. Okay. I can't remember what you said. The Desara and the Uretex, were those lightweight meshes?

A. So the Uretex was 81 grams per meter squared. So that was lighter than all the others. So if you take a look at all the current slings that are on the market, they're all at about 100. Boston Scientific, Desara, Align.

Q. And TVT®?

A. Yes, and they're all too heavy.

Q. Okay.

A. They're all too heavy.

Q. Everything that's on the market today is too heavy?

A. Everything that's on the market is a problem.

Q. Is the pore size for the -- not counting you're spreading it out when you implant it, is the pore size acceptable on the Desara as far as you're concerned?

A. Yes.

Q. Could you do the same spreading out thing with the TVT®?

A. You can't.

Q. Why?

A. Because the material frays. It's not just the mesh. It's not just the filament that's woven. It's the weave configuration, it's all proprietary.

So the first thing I did when TVT® was cleared was I pulled on it on a piece of paper. Oh, my God, it's falling apart. And that's why I didn't want to try it.

Q. It was falling apart, or what do you mean by that?

A. Yeah, it was -- when you --

Q. Pieces were coming off?

A. Pieces were coming off. Drastically.

Q. Have you read any study that the TVT® mesh falling apart, pieces coming off it, have been a clinical problem for anyone?

A. I've read in the Ethicon

documents that people complained that it was fraying.

Q. Have you read any published scientific literature where fraying and the TVT® mesh falling apart was recognized to be a problem?

A. Not yet.

Q. Okay. Talking about the Ethicon documents, do you, as a scientist -- well, first of all, have you seen any Desara internal documents?

A. I have not.

Q. Okay. Have you seen any BARD internal documents?

A. Not for slings.

Q. About their slings?

A. Not slings, no.

Q. Do you generally in reaching medical opinions rely upon internal e-mails and internal documents?

A. No.

Q. Have you written -- have you published in the medical field?

A. Yes.

Q. Have you ever cited an internal document when writing in a peer-reviewed journal?

A. No.

Q. Do you think citations of internal company documents in a peer-reviewed journal would be acceptable?

A. No.

Q. Okay. Have you ever been a reviewer?

A. Yes.

Q. Okay. And if you were given a paper that based opinions upon internal company documents, would you reject that paper as a reviewer?

A. It's a good question. I don't know what I would do. I would find it very different because you don't normally have that.

Q. Do you believe that you gave a fair representation of the overall Ethicon documents that you cited in your paper?

A. Yes.

Q. How many Ethicon documents did

you review?

A. I reviewed everything they sent me. I can't even tell you.

Q. That's a key part.

Did you review anything that wasn't sent to you by a lawyer, an Ethicon document that wasn't sent to you by a lawyer?

A. No. I wouldn't have access to it.

Q. Do you know how many they sent you?

A. Documents?

Q. Yes.

A. Thousands and thousands of pages.

Q. Is everything they sent you on the thumb drive or the CD, all the Ethicon documents they sent you on the CD or the thumb drive?

A. I believe that's what Mr. Matthews said.

Q. Do you know whether there were Ethicon documents that weren't sent to you that would paint a different picture than

what you've cited in your report?

Do you know that?

A. I don't know that.

Q. Were you given any testimony of Ethicon witnesses to review?

A. Yes.

Q. Okay. Was that also sent to you by the lawyer?

A. Yes.

Q. Is what was sent to you also on the thumb drive and the CD?

A. I've not seen the thumb drive.

Q. Okay.

A. I've not opened it. The CD, I believe, are my reports only.

Q. Does your report refer to all of the deposition testimony that you've been given?

A. No.

Q. Okay. How do I know which testimony you've been given?

A. I guess it's on the thumb drive.

Q. Okay. And so if there was --

did you read all of the Ethicon testimony that's been given?

A. Yes.

Q. It was on the thumb drive?

A. Yes.

Q. Every word of it?

A. To the best of my recollection, yes, sir.

Q. Okay. Do you know whether you were given all of the Ethicon testimony about these documents?

A. I don't know.

Q. Okay. In order to do a -- strike that. Back up.

To give a fair and balanced report, it would not be appropriate to cherry-pick from Ethicon testimony or Ethicon documents, true?

A. True.

MR. BALL: I like to take a break every hour.

Is that okay with everybody?

MR. MATTHEWS: You're right in the middle of a question.

MR. BALL: No, I was done with that question.

MR. MATTHEWS: Yeah, that's fine.

(Off the record at 10:04 a.m.)

QUESTIONS BY MR. BALL:

Q. Doctor, your reports that have been submitted in this case, Exhibits 2 and 3, you would not submit those reports to a peer-reviewed journal for publication, true?

A. They're not prepared for publication, no.

Q. And you would not use the same technique and approach in preparing those cases that you would if you were preparing a scientific paper to be presented to colleagues, true?

A. Yes. This is completely different.

Q. Okay. Now, the fraying that you mentioned, did the Uretex have any of that propensity?

A. No, it had a weave characteristic that I look for. So after

TVT® came out -- and I remember it was Will Irby that came and talked to me about it -- I didn't find another product that I thought met my characteristics, qualifications -- the characteristics of the Mersilene, until I saw Uretex, and the weave was in such a way that it did not fray.

Q. Now, was the Uretex heavier or lighter -- excuse me, the Mersilene, was that heavier or lighter?

A. Much lighter. 33 grams per meter squared.

Q. And why was it that the Mersilene -- what about it caused it to deteriorate early as you said earlier?

A. Well, I don't know that it deteriorated early. I didn't have those issues. But as it became more important to have Amid-type classifications -- and the Amid classification really was very important after the Gore-Tex because you needed 75 microns or larger to have macrophages fight the infection.

Q. Mersilene had that, didn't it?

A. It did, but it was multi-filament and that was the problem with it, and I wanted to do the best for my patients, and knowing that, I switched.

Q. So the standard became -- the acceptable standard was to use a lightweight, monofilament, macroporous mesh for slings, correct?

A. Macroporous, monofilament. The weight issue really didn't become important for some time after that.

Q. Would you classify all of the Uretex and the TVT® and the Desara all as lightweight or heavyweight?

A. They're all heavyweight.

Q. Are they recognized in the medical community to be heavyweight or lightweight?

A. Heavyweight.

Q. Okay. Now, as we've said earlier, obviously, at least hundreds, and probably thousands, of surgeons have used TVT® for SUI, true?

A. Yes.

Q. Okay. Are you critical of all of those surgeons for using a product that should never have been on the market?

A. I don't think they knew all of the things I knew or have my experience so I can't be critical of them.

Q. And by your experience, that means the one or two times you tried it?

A. No. No. No.

My experience with being a surgeon of last resort that sees patients that have problems.

For example, even in this community, Dr. Klutke was a preceptor for TVT®, and he would do surgery on patients, and those patients would have a problem. And they would then come to me. And I frankly would ask because Dr. Klutke was a professor of urology. He was one of the earlier adapters of the TVT®. He went to France and all of those things. And I am not sure he knew how to deal with the complications or I'm not sure exactly why, but those patients ended up with me, and I started to see a

pattern of problems. The more I did that, the more patients found out and more docs found out I could help these problems and pretty soon I'm in the situation I'm in.

Q. Have any of the complications that you've seen with the TVT® been related to improper surgical technique?

A. They follow the technique that's described. When I read the op notes, it reads like the way Ethicon set up the IFU.

Q. Well, can a surgeon attempt to follow what is set forth in the Ethicon IFU and make a mistake and not -- and then that leads to a complication?

A. They can change a technique like I've changed it, but can that be a mistake in the hands of others? I assume so.

Q. So is it fair to say that your opinion that the TVT® should never have been sold based upon you using it one or two times and -- the fact that it was based primarily upon using it one or two times and what you see from the people with complications?

A. Would you repeat that?

Q. Yeah.

Is your opinion that the TVT® never should have been on the market based upon the one or two times you tried it and the complications you've seen with people that have come to you postsurgery?

A. Plus everything that I've read to date.

Q. What is it that you've read to date specifically that -- or what are the two or three things you've read to date that are most important to you in your opinion that it never should have been on the market?

A. So I'm having a little difficulty even in my own practice anymore using polypropylene knowing that there's a chronic foreign body reaction, knowing that polypropylene degrades. I don't know how I'm going to personally deal with that. I'm going to have come up with an alternative source. Maybe going to completely cadaver types of slings.

But knowing what I know now after reading all of this, knowing that there

were alternatives available for different products to be developed, I may have put in a bunch of slings and I may have, you know, done it for -- not knowing what the consequences were.

Q. Did Mersilene have a foreign body reaction?

A. It did.

Q. What was it made out of?

A. Polyethylene terephthalate.

Q. Was the foreign body reaction any different with Mersilene than with polypropylene?

A. I'm sure it's different.

Q. Worse? Better?

A. I don't know. I haven't seen any data on that.

Q. You mentioned foreign body reaction.

The other thing was, what, deterioration of polypropylene, is that what you said?

A. Yes.

Q. Did Mersilene deteriorate?

A. Not like polypropylene.

Q. Okay. So the polypropylene slings that you've used, aside from the one or two times with TVT®, essentially are the Uretex and Desara?

A. Yes.

Q. And they're subject to chronic foreign body reaction?

A. Yes.

Q. They're subject to deterioration?

A. Yes.

Q. You're still using them?

A. I am.

Q. Have for 13 years?

A. Yes.

Q. Implanted thousands?

A. Yes.

Q. Have you ever told any of your patients that you shouldn't have used polypropylene because of its deterioration or foreign body reaction propensities?

A. I'm saying that to patients now.

Q. And you started that a year or so ago?

A. Yes.

Q. What problems does the chronic foreign body reaction cause?

Let me withdraw that question and ask something better.

You can have a chronic foreign body reaction that doesn't cause any symptoms to the patient, true?

A. I'm sure you can to some extent, yes.

Q. And are you aware of any studies that have shown that a chronic foreign body reaction causes problems for patients?

A. Yes.

Q. What is that?

A. The problem is that it contracts. The chronic foreign body reaction and the -- a lot because of the pore size it creates this granuloma-type of effect and entraps little nerves. Instead of the pores being far apart and the nerves being padded

with fat infiltration, the nerve gets squeezed over time and that chronic inflammation continues to contract and it creates contraction in the vagina. So when you examine these patients, you feel a tethering effect like a banjo string or a rope, and that causes pain.

Q. Do you have acute or chronic pain with Desara and Uretex slings?

A. Can you? Yes.

Q. That's a risk?

A. Yes.

Q. And acute or chronic pain with intercourse, is that a risk of SUI surgery with Uretex or Desara?

A. Can I qualify the answer?

Q. You can say yes first and then qualify.

A. Yes, you can, but that's because they follow the manufacturer's instructions and don't do exactly what I do.

In my patients, it's basically, no, it doesn't happen.

Could you have it happen? One

in a thousand, one in 22,000.

Q. With your technique?

A. With my technique.

But it's not 10, 12 percent.

Q. So let me make sure, as I go through these questions what I'm asking for is with the Desara or the Uretex, if you follow the manufacturer's instructions and you use the manufacturer's technique.

A. Okay.

Q. That's the premise.

A. Okay.

Q. All right. So can you have acute and chronic pain with Desara and Uretex?

A. Following the manufacturer's technique, yes.

Q. Can you have acute and chronic pain with intercourse with Desara and Uretex?

A. Yes.

Q. Can you have vaginal scarring with Uretex and Desara?

A. Yes.

Q. Can you have infection?

Let me -- is infection a risk with surgery using Uretex and Desara?

A. Yes.

Q. Are urinary problems such as urinary frequency, urgency, dysuria, retention, obstruction and incontinence, are those potential risks with Desara and Uretex?

A. Yes.

Q. Organ and nerve damage, are those potential risks with Desara and Uretex?

A. Yes.

Q. Postoperative bleeding, is that a potential risk with Uretex and Desara?

A. Yes.

Q. Wound complications, is that a potential risk with Desara and Uretex?

A. Yes.

Q. Inflammation, is that a potential risk?

A. Yes.

Q. Fistula formation, is that a potential risk with Uretex and Desara?

A. Yes.

Q. Neuromuscular problems with the

pelvic floor muscles, is that a potential risk with Uretex and Desara?

A. Yes.

Q. Lower extremity pain, is that a potential risk?

A. No.

Q. Abdominal pain, is that a potential risk?

A. Yes.

Q. Need for additional surgery, is that a potential risk with Uretex and Desara?

A. Yes.

Q. Failure of the procedure, is that a potential risk with Uretex and Desara?

A. Yes.

Q. Foreign body reaction is a potential risk, chronic foreign body reaction with Uretex and Desara?

A. Yes.

Q. Exposure or erosion or extrusion, is that a potential risk with Desara and Uretex?

A. Yes. Again, all of those following the manufacturer's instructions for

implantation.

Q. And contraction or shrinkage of tissues, is that a potential risk with Uretex and Desara?

A. Yes.

Q. All right. Now, do you have any opinion as to what the relative risks are of those things we went through for TVT® versus Uretex and Desara slings?

A. Following the manufacturer's instructions?

Q. Yes.

A. Okay. They're slightly higher for TVT® because of the weave design of the mesh that upon any traction it frays and literally falls apart.

Q. This falling apart, have you actually seen it fall apart?

A. Oh, yes.

Q. This is in your surgeries you do?

A. No, I have samples of mesh that I've -- I acquired almost all the mesh samples I could possibly acquire to

understand them.

Q. This is mesh that's been in the body?

A. No. No. No.

Q. Okay.

A. Expired, donated from reps.

Q. Okay. Have you seen any mesh, TVT® mesh, falling apart in the body?

A. Yes. Yes.

Q. In your explanting procedures?

A. Yes.

Q. And if I asked this, I apologize.

Can you point me to any medical literature where someone has described a problem with the TVT® mesh falling apart as you describe it?

A. You mean the fraying?

Q. I mean, the falling -- you said that it falls apart.

I want to know has anybody written a medical paper that has said, you know, this TVT® mesh falls apart when it gets in the body.

Have you read that anywhere?

A. I can't recall.

Q. You can't point me to anything?

A. I cannot at this time, no.

Q. And it's certainly not in your report, true?

A. No.

Q. True?

A. True.

Q. So your only basis for saying that in the body the TVT® mesh frays so badly that it falls apart is what you've seen from your explant procedures, true?

A. Yes.

Q. Are there any samples of that in your report?

A. No.

Q. Do you have any -- if we want to say, I don't know, I've never seen such a thing, I've never heard of such a thing, we wanted to see it, what do you do?

A. I have pictures.

Q. You have pictures that aren't in your report?

A. Yes.
Q. Okay.
A. Lots of pictures.
Q. And these are -- this is mesh falling apart, not as a result of you taking it out?
A. No.
Q. Why do you think nobody else has ever written about that?
A. I don't know. I haven't written about it.
Q. Okay. So other than this tenancy -- and the reason you think it frays and falls apart is because the edge -- tell me why you think the TVT® frays and falls apart as you describe it and the other ones don't.
A. It has to do with the weave.
Q. Okay.
A. So when TVT® was mechanically cut early on it was clear before they made it blue, it was harder to see it. But when it became blue, it became very visible in the tissues. I have a clear recollection from

years ago on a slide where I'm not removing the sling, but I'm fixing the woman's prolapse after she had her sling and have the vaginal wall open and you can see a hairpin loop of mesh attached in there.

I probably wouldn't have seen that when it was clear. I did see it when it was clear when I first handled it early on.

Q. So --

A. So it has to do -- you know, this mesh starts as a suture, and then it goes through a machine that knits it into a big sheet, and then it gets cut.

So TVT® and the Boston Scientific product are somewhat similar in the fact that when you first cut the TVT® early on when it was mechanically cut, the edges would fray. It was sort of like cutting a sweater that your grandma knit and you got a cut and it started to unfray, but it wasn't on the body like a sweater. It's a strip of mesh so when you cut it and you pull on it, they would pop off.

Q. So the problem with the weave

that causes this fraying and falling apart problem is the way it's cut on the edges, is that what you're saying?

A. Yes. And that's why it went to laser cut afterwards.

Q. Does the laser cut have the same problem?

A. To a less extent.

Q. Okay. So is the laser-cut mesh, do the risks of that outweigh the benefits so that it never should have been put on the market?

A. Yes.

Q. Okay. For what reason?

A. It's the same thing. The elasticity. It still pops apart where the laser seals it a little bit, but if you put traction on it, it pops apart.

Q. So the problem you have -- I've heard two problems you have with the mesh itself. We've talked about the instrumentation issue, and we've talked about the technique.

A. Yes.

Q. The mesh itself, what I've heard, is that you have two criticisms of the TVT® mesh: One is whether it's mechanically cut or laser cut, the edges are -- or the weave and the edges are susceptible to fraying and falling apart in the body, that's one, right?

A. Yes.

Q. And then number two, the pores, once they're in the body, are not big enough to allow the tissue ingrowth?

A. Yes.

And three, and this applies to all polypropylene, including the polypropylene I'm implanting, was not very clear when this all came out, when this product first came out, that polypropylene degrades.

Q. Now, are you aware of any medical literature where someone has identified degradation of TVT® polypropylene as causing clinical problems for patients?

A. Well, the Clavé study looked at polypropylene TVT® and studied that that

causes contraction and fibro -- a chronic inflammation and scarring and shortening and shrinkage and possibly erosion.

Q. So your interpretation of the Clavé paper is that it says that degradation of TVT® polypropylene produces clinical problems for patients?

A. Yes.

Q. All right. Any other paper besides that?

A. With TVT®?

Q. Yes.

A. Not that I recall off the top of my head.

Q. Okay. Now I'm going to broaden it. You anticipated that.

Are you aware of any papers that say polypropylene in general in use with vaginal surgery degrades to such an extent that it causes clinical problems for patients?

A. All mesh, or mesh in general, right?

Q. Yes.

A. Yeah.

I am. Let me refresh my memory.

Q. Let me ask this.

A. Yes.

Q. Do you cite any paper in either of your reports, Exhibits 2 or 3, concerning TVT® or Gynemesh® that to support the proposition that polypropylene degrades and causes clinical problems for patients?

A. I don't know that there's any papers that say there's clinical problems.

Q. Okay. Now, by the way, how many hours did you spend just preparing for this deposition?

A. 20.

Q. Okay. We went through a long list of potential risks of sling surgery using polypropylene, right?

Remember we compared -- or we talked about Uretex and Desara and all of the risks they have.

Does TVT® have a greater risk than Desara or Uretex with respect to any

complications?

A. Yes.

Q. Potential complications?

A. Yes.

Q. Which ones?

A. Cording, roping, because of the fraying that occurs and loss of fibers.

Q. Okay. And then what complication does that cause for the patient?

A. Retention. It can cause pelvic pain. It can cause exposure, erosion.

Q. Okay. Do you have an opinion as to whether the rate of exposure and erosion with TVT® is higher or lower or the same as compared to Uretex and Desara?

A. I don't see many patients that have a Desara problem. I see very few patients that have a Uretex problem. I do see many patients with TVT® problem.

Q. Do you have any notion as to how many TVT®s have been implanted versus Desara and Uretex?

A. I'm sure there's a lot more TVT®s.

Q. Right.

So it's not really fair to compare numbers of problems you see with Desara and Uretex versus TVT®, true?

A. Sure. Yes.

Q. Okay. Are you aware of any study that says that TVT® with respect to any of the complications of -- the potential complications of SUI surgery with mesh has a greater propensity for any of these calculations than competitor products?

A. That study hasn't been done.

Q. And do you have an opinion -- do you believe you have sufficient information to state an opinion as to the comparative risks of TVT® versus Uretex and Desara with respect to any of these complications?

A. My opinion is based on the number of patients I see with complications with all slings. And TVT® is much higher than the others.

Q. Okay. But you also have just agreed that there are far -- there have been

far more TVT®s implanted in the population than there have been Desara and Uretex, true?

A. Yes.

Q. Okay. 10 or 20 times as many, right?

A. I wouldn't know.

Q. Okay. So do you believe you have a valid scientific basis to state that the complications with TVT® are greater than Uretex and Desara?

A. Yes.

Q. Okay. And what is that scientific basis?

A. It's based on my entire knowledge, my training, my expertise as a vaginal surgeon, the review of all of the materials that I've had to review, reading as much literature as possible. There are very few papers that talk about complications from slings, and there's very few papers, if any, that compare one sling over the other for complications.

Q. Well, if there's very few papers, how can that be a scientific basis?

I guess that's my problem.

I understand that you in your practice have seen more TVT® complications than Desara and Uretex. I understand that. Okay. But you've just said there's a whole lot more TVT®s out in the market.

So can you point me to any specific -- I don't mean general, my training and experience. Can you point me to any specific scientific basis that you have for stating the opinion that TVT® has a greater risk of complications than Desara or Uretex?

A. There's scientific evidence that looks at what happens to the different meshes with force.

Q. Okay. What is that?

A. I am sorry.

Q. What is that scientific evidence?

A. That is a paper that I believe was done by Wylie to put force on multiple different slings and look at the way these properties behave outside of the body.

Q. So do you have any -- and I

wasn't clear, and I'll make it.

Can you point me to any scientific literature that says in the body TVT® has more risk of complications than Uretex or Desara or any other type of polypropylene sling?

A. Not at this time.

Q. Okay. Do you have any -- and I think -- do you have any estimate as to what percentage of patients with TVT® slings have had problems with long-term inflammation?

A. Ask this again, please.

Q. Do you have any -- and I think -- let me just ask a global question.

You list in your report at page 5 -- okay, let's go to your report, your TVT® report, page 5.

Okay. Paragraph A, under the list of opinions, right?

A. Yes.

Q. And you see you say the mesh in TVT® can cause foreign body reaction, inflammation, et cetera.

Do you see that?

A. Yes.

Q. Okay. Do you have any opinion as to what percentage of the patients who have had a TVT® implanted have problems of chronic foreign body reaction, inflammation, fibrotic bridging, mesh contraction, fraying, particle loss?

A. All of the patients I see in my practice.

Q. In your explant practice?

A. Yes.

Q. I appreciate that, but my question was of all of the people that have had them implanted, do you have an opinion as to what percentage have had any of those problems?

A. I don't.

Q. Okay.

A. I have a guesstimate.

Q. I'll hear it even though I don't think it's admissible, but go ahead.

A. 30 percent.

Q. And what's that based on?

A. On the shrinkage rate of the

polypropylene mesh that it shrinks 20 to 40 percent. So about 30. So about 30 percent of those patients are going to have a problem.

Q. What's that 20 to 40 percent shrinkage rate based on?

Is that in vivo or ex vivo?

A. Well, in vivo in animals. It's not in vivo in patients.

Q. So do you have any data that talks about the shrinkage rate of mesh, of a TVT® mesh, in a woman?

A. No.

Q. And a woman can have foreign body reaction and have no symptoms, true?

A. Some might, yes.

Q. A woman can have fibrotic bridging and have no symptoms, true?

A. I haven't seen any.

Q. I didn't ask whether you've seen any.

Can that occur?

A. I haven't seen everyone. I want to be truthful and precise, but just as

I don't know --

Q. Well, there's varying degrees of fibrotic bridging, aren't there?

A. I think fibrotic bridging is fibrotic bridging. If it comes together as granulomas, it's granulomas.

Q. Are there varying degrees of mesh contracture?

A. It can vary, 20, 30, 40 percent.

Q. Down here in opinion C, Ethicon failed to adequately describe to physicians how to properly tension the TVT®.

Does this go back to the technique criticisms you had?

A. That's actually in the IFU. In the IFU in one place it says, "minimal tension," and in one place it says, "no tension." It talks about doing the placement under a local or under a general. Under local at 300 MLs they're supposed to cough until there's a drop. So that is a tensioning approach. But later on they say, "no tension" and "minimal tension." So it's

not -- it's not very precise.

Q. Did you read the IFU before you implanted the TVT® a number of years ago?

A. Yes.

Q. Do you believe that experienced surgeons who perform SUI surgery with mesh in 2010 and before were aware that a potential complication was acute or chronic pain?

A. I don't think they knew about it, no.

Q. What about acute or chronic pain with intercourse?

A. No, I don't think they knew about it.

Q. So you don't think experienced surgeons before 2010 knew that acute or chronic pain with intercourse was a possible complication with mesh SUI surgery?

A. May I ask what would you call an experienced surgeon?

Q. Somebody that does sling surgery on a regular basis.

A. I don't know what a regular basis -- once a week?

Q. You can't answer the question?

A. No. I'm trying to ascertain what a -- I don't think an experienced surgeon is someone who does one a week. I think an experienced surgeon would be someone who does three, four a week. And even I, when I was first learning about these slings, wouldn't have thought that a patient would have had pain with intercourse from a polypropylene sling.

And I saw many patients that went to their doctors and all they heard was a common phrase, "It's not the mesh, it's not the mesh, it's not the mesh." So the examination has to be very specific and precise on where the mesh is placed. And when you do that and you listen to these women, you see that that is the cause, confirmed by my own removal and their pain goes away.

Q. Was pain with intercourse a risk with Mersilene?

A. I didn't think it was.

Q. Is it?

A. Knowing what I know today, probably. But it's a lot softer. It's lightweight. It's 33 grams per meter squared. It's not 100. This lays very flat. You can't feel it so it drastically less.

Q. Is pain with intercourse a risk with the Burch procedure or the MMK procedure?

A. No.

Q. Paragraph E, Ethicon failed to inform physicians of certain patient populations may be more prone to experience adverse outcomes or higher frequency or severity of risk.

What patient populations fall into that category?

A. Patients that have excessive scarring, and you don't know who that is, but there are patients that formed keloids, for example.

The only warning is in patients that are growing or pregnant are going to have a delivery. So patients that are on steroids, patients who are diabetic, women

that have chronic obstructive lung disease, elderly women that may not heal right. A certain percentage of smokers.

Q. Those are all ones that should not have --

A. Those are ones that ought to be warned that they may have a higher frequency of complications.

Q. Autologous and cadaveric slings, have they always been available for SUI?

A. Autologous sling was actually described in 1907 by Von Giordano was actually an autologous sling.

Q. Yeah, I don't want to go back quite that far.

Have they been in regular use for how long?

A. I think they were really popularized in the '40s by Aldridge.

Q. So in the 2000s, were doctors regularly performing sling procedures with cadavers and autologous grafts?

A. I think that when TVT® came

along, it changed the mindset of everyone. You don't need to harvest. You don't need to take the extra time in the OR. This is quick and easy. Here you go. It's a whole kit; put it in. The report by Ulmsten was you could do this in 25 minutes under local. The patient goes home the same day. It all sounded really, really good, and a lot of people abandoned doing autologous slings.

Q. As far as you understand, the Desara sling is safe?

A. The way I use it, yes.

Q. It's not safe if you follow manufacturer's instructions?

A. No.

Q. And the Uretex sling was safe in your technique, but not using manufacturer's instructions?

A. Correct.

Q. Okay. So down here in paragraph F where you say that there were safer alternative options available, what available options were safer?

A. Burch, autologous slings,

cadaveric slings.

Q. Do you still offer patients Burch as an alternative if you're not going to be doing an abdominal surgery?

A. I do.

Q. Has anyone chosen that?

A. One patient.

Q. So as you're sitting here today, do you believe a Burch procedure is a safer procedure for a patient than any type of mesh sling procedure?

A. Long term, yes.

Q. Okay. And do you believe autologous and cadaveric slings are safer procedures than any kind of mesh?

A. Yes.

Q. Do you tell your patients that, do you tell your patients that long -- when you're having this discussion with them and giving the alternatives, do you tell your patients that you can either have a mesh sling, or you can have an autologous sling, or you can have a cadaveric sling, or you can have a Burch procedure?

Those are your four alternatives, right?

Is that right?

A. And some urethral plication.

Q. And what is that, briefly?

A. Briefly, it's the pubourethral ligaments that are replaced by TVT®, which is the theory of Ulmsten and Papa Petros. Instead of replacing them with an implant, you grasp them and you suture them underneath the midline and create a in-situ sling.

Q. So it's kind of a native tissue repair, so to speak?

A. You could call it that, yes.

Q. It's not using any kind of outside material?

A. Correct.

Q. Okay. So that's the fifth one you offer?

A. Yes, if their urodynamics are not severe incontinence.

Q. And do you believe that's a safer alternative than any type of mesh?

A. That is the safest, yes.

Q. Okay. So when you're sitting there talking to a patient and you're giving them these five alternatives, do you tell them that all of the alternatives are safer long term than a mesh procedure?

A. I tell them that I don't know what the long-term complications from a sling are going to be. I tell them that there's a failure from the native tissue repair, that the Burch procedure is more invasive, that the harvesting a piece of their own body is a little invasive, but it's not terribly invasive. A Burch is more invasive than a sling, and that a cadaveric sling is the same sequence of steps as putting in a polypropylene sling.

And I let them pick.

Q. And then do you tell them that long term all the alternatives, other than a mesh sling, are safer?

A. Yes.

Q. Okay. Is there literature that you can point me to, reliable scientific literature, that says that all procedures for

SUI, all these other procedures, are safer than any type of mesh sling?

A. No, there's literature that says there's alternatives. I don't know that anyone has done a head-to-head comparison long term for these procedures the way that they do surgery.

When I'm counseling my patients, it's the way that I do surgery and even the polypropylene slings that I place, I do differently.

Q. My question is are you aware of any literature, scientific, published literature, that says that mesh slings are the least a safe alternative for SUI surgery long term?

A. No.

Q. Okay. In fact, are you a member of any organizations?

A. Yes.

Q. What?

A. ACOG, Society of Gynecologic Surgeons, AUGS, AAGL.

Q. Do any of those organizations

publish guidelines or practice parameters or position statements about SUI surgery?

A. I think AUGS and SUFU has put something out there.

Q. And do either of those publications state that mesh surgery is the gold standard for SUI treatment?

A. They do call it the gold standard.

Q. What does the gold standard mean to you?

A. What it means to me is if you take a group of surgeons that do the same procedure, that they have uniform results and uniform complications. That's what the gold standard means to me.

Q. It doesn't mean it's the preferred procedure?

A. I think that the way that it's used it implies that, but that's not what it means to me.

Q. So the gold standard to you, if it's published in these position statements by these organizations that you're a member

of, does not mean that it's the preferred procedure?

A. That's not what it means to me. I've seen -- I remember looking at that and calling it the gold standard and years ago the Burch was the gold standard and the sacrocolpopexy is the gold standard. And what I've always taken that to mean is when we treat women across the country, across the planet, that the procedures that we do in the hands of many are safe, which is what this data is supposed to extrapolate and tell us, the risk/benefit ratio. So that if someone who is a very good scientist does a very well-designed study and comes up with a percentage of cure, that that would then extrapolate to the hands of other surgeons.

Q. Do you believe that mesh sling surgery is the gold standard for the treatment of SUI?

A. I believe slings are the gold standard.

Q. That wasn't my question.

A. I know.

Q. My question is do you believe that mesh slings are the gold standard for -- well, strike that.

The AUGS does say that mesh slings are the gold standard for treatment of SUI, true?

A. It says, if I can be specific, multi-incision slings. So there's single-incision slings. Those aren't really included.

Q. And the TVT® is not a single incision?

A. It's not a single-incision sling.

Q. Do you agree that the AUGS says that multi-incision polypropylene slings are the gold standard for treatment of SUI?

A. And I'm going to answer that question in, no, I don't believe it's the gold standard.

Q. First of all, it's a two-part question.

First of all, do you agree that's what the AUGS says?

A. It says that, yes.
Q. And number two, do you agree with that statement?
A. I do not.
Q. And because?
A. Because they're talking about two completely different types of midurethral slings. So first is the retropubic TVT®, and the second is the TOT. So if you lump those two together, those are completely different slings even though they're multi-incision. They have a completely different set of cure and complication profiles.
Q. And you believe that the obturator slings are less safe than the retropubic?
A. If we define -- how do we define safe? Bladder perforation, they have less bladder perforations. They have --
Q. Overall safety.
A. Overall safety?
Q. And efficacy.
A. They are less efficacious. They're safer in the sense that you don't

enter the pelvic bowl and you injure structures, but they have their own unique set of problems with the leg pain, as you mentioned in one of your questions, with limb pain as it transverses the obturator muscles and the adductors.

So they lump those two different kinds of slings as midurethral slings, but they're separate and distinct beasts.

Q. A retropubic midurethral polypropylene sling, is that the gold standard as far as you're concerned for the treatment of SUI?

A. I think the gold standard is being able to do a sling. That's what really works.

Q. But again --

A. Can it be out of polypropylene done a very specific way like I do? Yes.

But the way that the gold standard is set in that statement it's using the manufacturer's instructions, and I don't think that those slings are the gold standard

being placed the way that the company suggested it be placed.

Q. Do you classify the TVT® mesh pore size as macroporous or microporous?

A. It's less than 1 millimeter, so it's micro.

Q. In the body or outside the body?

A. Inside the body.

Q. Okay. So under the Amid classification, are the measurements made inside of the body or outside the classification?

A. Amid classification is 75 microns. Everything is macroporous by that definition.

Q. So are you aware of any classification system other than the Amid system for classifying pore size in mesh?

A. No.

Q. All right. Under that classification, the mesh in TVT® is macroporous?

A. Yes.

Q. Right?

Okay. How did you decide which Ethicon testimony to cite in your report and which Ethicon documents to cite in your report?

Let me back up. First of all, are you aware that there have been thousands of pages of testimony from Ethicon employees?

A. I would believe so.

Q. There would be millions of pages produced from Ethicon?

A. I wouldn't doubt it.

Q. And in your report, you cited a few pieces of testimony and cited several documents, right?

A. Yes.

Q. How did you decide which pieces of testimony to cite and what not to cite and which documents to cite and what not to cite?

A. I cited every -- I gathered everything that I thought was relevant from what was sent to me and cited it.

Q. Do you say anywhere in your report that laser-cut mesh -- I see where you

often talk about mechanically cut mesh can fray, et cetera, and release particles.

Do you have anywhere in your report that you refer to laser-cut mesh having that same issue?

A. Which issue was that? The fraying?

Q. Like on page 9 you say the mechanically cut mesh was known to rope, curl and deform, and the mechanically cut version of mesh could fray or release particles.

Do you have anywhere in your report where you say laser-cut mesh can rope, curl or deform or release particles?

A. Well, I didn't specifically state that, but it's implied.

Q. How is it implied?

A. Well, just because it's laser cut doesn't mean it's not going to fray.

Q. Do you say that in here anywhere?

I see where you specifically say the mechanically cut mesh will fray and have particle loss, et cetera.

Did you ever say laser-cut mesh will do that?

A. I may have been remiss in saying that.

Q. You mean in not saying that?

A. Not saying that, yes.

Q. When you take a -- when you explant a TVT®, are you able to tell whether it is laser cut or mechanically cut?

A. I can tell before because I have the implant log.

Q. Does the implant log specify mechanical cut versus laser cut?

A. It does.

Q. It says it on there?

A. Uh-huh. 810081 BL.

Q. That's the part number or whatever?

A. Yes. I am sorry, 41. 810041. The 81 is the TOT.

Q. I think you mentioned 34 TVT®s you removed last year?

A. Yes.

Q. Were you including all the

TVT®s or just the TVT® that's the subject of your report here?

A. Just the subject of my report.

Q. So TVT-Os and Abbrevos and whatever else would be on top of that?

A. That's different, yes.

Q. Of that 34, can you tell how many were mechanically cut and how many laser cut?

A. Yes, but I didn't separate them out.

Q. But just so we're clear, is it your testimony that the laser-cut mesh never should have been sold either?

A. Yes.

Q. The Desara and Uretex, were those laser cut or mechanically cut?

A. They're not -- they're neither.

Q. Okay. And do you ever have to cut a Desara to create exposed edges, a Desara and a Uretex?

A. No, just after implantation, the part that is above the skin, that's the only cut.

Q. Can you point me to any scientific literature that says that particle loss with mesh causes any clinical problems for patients?

A. No.

Q. Have you ever written in any medical operative report or medical record for any patient that you believe some of their clinical problems were related to particle loss from mesh?

A. Not in those words, no.

Q. Have you ever referred to particle loss in any way in any medical record for any patient?

A. Not at this time.

Q. In fact, do you know whether particle loss from TVT® mesh causes any clinical problems with patients?

A. I do.

Q. Okay. What's your basis for that?

A. It narrows the caliber, the diameter of the mesh, because the actual weave unravels. When it unravels, it loses

its configured design. It's a design flaw. It should not do that. There's other meshes that don't do that.

Q. I'm talking about particle loss. I'm not talking about fraying now.

Okay. I'm talking about particles actually breaking off.

Is that what you mean by particle loss?

A. Well, they're almost one in the same.

The reason the particles break off and they fray is because the actual weave design of the mesh is flawed. And because it's flawed, when you put traction on it, the actual heat -- however they weave this, the curly Q breaks off. That loses that attachment holding the two sutures together, and it frays.

Q. So do you believe there are situations where actual particles of the mesh separate from the body of the mesh?

A. Yes.

Q. Okay. Have you seen that?

A. Yes.

Q. And has it ever -- well, I've already asked that question.

A. It's the only sling that does this. The other slings don't behave this way at all.

MR. MATTHEWS: Break time?

MR. BALL: Sure. Can I ask one more question before we break?

MR. MATTHEWS: Sure.

QUESTIONS BY MR. BALL:

Q. Can you point me to anybody else who has written a peer-reviewed medical paper that says TVT® has all of these problems with fraying and that type of thing that the other meshes don't have, like you just said?

Can you point me to anybody that has published something and agrees with that?

A. I don't think that they've compared it to other slings.

Q. So you can't point me to any paper that agrees with that statement you've

made, true?

A. Not at this time.

Q. True?

A. Yes.

MR. BALL: Okay. That's it.

We'll take a break.

(Off the record at 11:08 a.m.)

QUESTIONS BY MR. BALL:

Q. Now, have you ever -- let me get to your CV here. You want to get that out. I've got just a few questions about that.

It's attached, I think, to the back of -- have you ever published anything specifically about TVT®?

A. No.

Q. Have you ever published anything specifically about Gynemesh® PS?

A. No.

Q. Have you published anything about use of mesh in SUI surgery?

A. I published a paper looking at the recommendation of a sling with SUI diagnosis.

Q. Where was that published, or how long ago was that, let me ask that?
A. '95.
Q. Have you ever published that TVT® has all these problems and, therefore, should never have been sold?
A. No.
Q. Why not?
A. I've been busy taking care of people.
Q. Have you ever published that Gynemesh® PS -- strike that. Let me back up.
Do you believe Gynemesh® PS was so poorly designed it never should have been sold?
A. Yes.
Q. Have you ever published that opinion?
A. No.
Q. Same reason?
A. Yes.
Q. Have you ever stated in any kind of presentation to other doctors that TVT® never should have been sold?

A. No.

Q. Have you ever said that to any group of doctors about Gynemesh® PS?

A. No.

Q. Why not?

A. Don't normally get in front of a group of doctors.

Q. Well, I mean, you've presented abstracts five times in the last five years, right, according to your presented abstracts in your CV?

A. Which abstracts are you --

Q. Looking at part of your résumé or your CV that says "Presented Abstracts." The second page of your CV.

A. So that first one was sacrocolpopexy.

Q. No. What I'm asking, did you actually go out there and present your abstract?

A. I did not present it.

Q. On any of these first five that were 2011 to the present, did you do the presentation?

A. I did not.

Q. Okay. So one of them is mesh complications requiring removal of midurethral slings, oral presentation.

Did you do that?

A. Did not.

Q. Did you participate in whatever the materials were?

A. Yes.

Q. Do you have those?

A. What do you mean by materials?

Q. I assume when you make -- what was the format of this oral presentation?

Let me back up. Why would you be listed as giving an oral presentation in September of 2011 about mesh complications requiring removal of midurethral slings, if you didn't do it?

A. I did do it. I was part of the project, but I was not the one verbally presenting the project.

Q. Were you there?

A. No.

Q. Okay. So what was the project?

A. The project was looking at all the slings that had issues. It didn't single out TVT® at that time.

Q. Was that published in some manner?

A. No.

Q. Were there slides or anything to accompany this oral presentation?

A. I'm sure there were.

Q. Okay. Do you have those?

A. No.

Q. When did you decide that TVT® was so unsafe and never should have been sold?

A. Few years after it came out.

Q. Okay. So 2005 or before?

A. Around that time.

Q. So what about these invited -- here's an invited lecture, Perils for removal of mesh, roundtable discussion, did you attend that?

A. That, I did.

Q. Are there any materials from that?

A. No, that was simply a roundtable discussion.

Q. And at that roundtable discussion, did you say either Gynemesh® PS or TVT® was so unsafe it never should have been sold?

A. I didn't single out any manufacturer or any implant. The talk was designed at helping docs manage patients that had mesh complications.

Q. The same thing with the April 2013 roundtable in Charleston?

A. Yes.

Q. So you have had occasions where you've made presentations about mesh complications to doctors, right?

A. Yeah, it wasn't -- yes, I didn't consider that a presentation. I consider a presentation I get up at a podium and I give a talk. It was mostly at breakfast. Usually it's seven, eight people, two, three show up and, "How do you do this, how do you do that."

Q. But at none of these roundtable

discussions did you say that TVT® or Gynemesh® PS should never be used, true?

A. True.

Q. And there's no written materials for those roundtable discussions?

A. There was not.

Q. Now, do you have some role with training people, residents?

A. Yes, I do.

Q. Where is that done?

A. That's at Mercy.

Q. How many do you train per year or however it works?

A. The program is accredited for six residents at each level for four years, total of 24.

Q. So at any one time you're dealing with 24?

A. There's 24 residents there. It's one-on-one mostly when I'm dealing with them.

Q. But do you deal with all 24 of them throughout the course of the year?

A. Yeah.

Q. That's what I meant. I didn't mean you get all 24 together at once.

Have you ever told the residents they should never use TVT®?

A. Yes.

Q. Okay. Never use it?

A. No.

Q. And have you ever told them they shouldn't use Gynemesh® PS?

A. Yes.

Q. When did you start doing that?

A. I can't tell you an exact time. It's been years, but they see these patients in the operating room with me, and they get a sense of what they should do and shouldn't do.

Q. There's a book chapter on here, Chapter 18, Dekker, Inc., published in 2003.

Has that been updated since that -- ever?

A. It's not been updated.

Q. Okay. So it doesn't sound like you have; do you have anything in writing about mesh used for SUI or prolapse?

A. No.
Q. Besides the residents, have you told any other doctors that they -- that in your opinion they should not use TVT® slings?
A. Yes.
Q. How many?
A. The three or four that do slings at Mercy.
Q. Okay.
A. They ask me specifically what products they should use, and I give them my opinion.
Q. Okay. Anybody else?
A. Anyone who has asked me.
Q. Well, do they ask you what products you prefer, or do you affirmatively tell them, "Whatever you do, don't use TVT®"?
A. No, I think we have a discussion. They ask, you know, "How should I manage this, what product should I use, what approach should I use, how should I do it, which products are available." And I tell them what's available anymore out there is not many more manufacturers left, and I

recently had this discussion when AMS pulled their product and BARD pulled their product.

Some of the urology colleagues and gynecology colleagues asked what they should do and what my opinion was. I didn't overly twist their arm to use it or not to use it. I presented the pros and the cons of what I do, how I do it and why I do it and what's available out there, and I let them decide. Even though I feel strongly that TVT® is not a good product, I didn't, you know, ram it down their throat and say, "Don't use it."

Q. What is on the market today for SUI mesh besides TVT® and Desara?

A. Advantage Fit.

Q. And that's a Boston Scientific product?

A. Yes.

Q. Do you believe that's a safe product?

A. No, it's not as good as Desara.

Q. Okay. And what's unsafe about it?

A. It has the same issue with the round straw adaptation to the flat sling. I think it's pretty easy. We both learned in second grade that you can't put a square peg in a round hole. So all of these trocars create a round opening and then they put a square piece in there and it immediately causes it to roll. It's a design flaw in every manufacturer.

So the only way to get around it is to have a sling that allows to you do surgery, open those spaces up, lay the sling nice and flat, and the only product out there, and it doesn't fray, is Desara.

Q. Does the Advantage sling have a fraying issue?

A. Yes.

Q. All right. So you're critical of the Boston Scientific Advantage product both because it has an issue of fraying and because it has an improper instrumentation?

A. Yes.

Q. And does it also, in your view, recommend inappropriate technique?

A. Yes.

Q. So Advantage, Desara, TVT®, are there any other polypropylene sling products on the market that you're aware of?

A. Coloplast.

Q. Okay. And what's the name of theirs?

A. The retropubic one is called Supris.

Q. Have you used it?

A. I have not.

Q. Does it have an instrumentation problem?

A. It has less of an instrumentation problem.

Q. Okay. Do you believe it has an unsafe instrument with it?

A. Not as much because the sling --

Q. I didn't ask as much. I'm not there to ranking them yet. I'm just saying do you think it has a safe instrumentation or not?

A. No, it does not.

Q. It does not?
A. It does not.
Q. Okay. Does it have a safe recommended technique?
A. It has a recommend technique.
Q. Is the recommended technique safe?
A. Not in my opinion.
Q. Okay. And then the mesh itself, is the mesh itself safe?
A. No.
Q. Okay. So on the market today, is there anything else? That's the four.
A. There's I-Stop. I don't see too much of that. Every now and then I get a patient that has a problem. I don't know who -- I don't know anyone that uses it around here. These patients come from far away.
Q. So the four that are used with some regularity in the United States are the -- what did you say the Coloplast was called?
A. Supris.

Q. The Supris, the Advantage, the TVT® and the Desara?

A. Yes.

Q. Okay. And all of those, as far as you're concerned, have unsafe instrumentation?

A. Yes.

Q. And all of them have an unsafe recommended technique?

A. Yes.

Q. And all of them, except the Desara, have an unsafe mesh?

A. Yes.

Q. Okay. And maybe is the Desara a safe mesh or not?

A. Yeah, I was thinking of the difference between the Supris and the pore size and the configuration and the diameter, comparing that to the TVT® and then comparing all of it to each other real quick.

Q. So does Desara have a safe or unsafe mesh?

I'm not talking about the instrumentation. I'm not talking about the

technique.

Is the mesh itself safe with the Desara as far as you're concerned?

A. The mesh has the same problem, it is polypropylene and degrades.

Q. Do you consider it reasonably safe, the mesh itself?

A. Same category as all the others.

Q. So is it fair to say that all of the meshes that are on the market today, you consider all of them for SUI surgery to be unsafe?

A. At this point in time with everything I've reviewed and everything I've learned, they are not safe.

Q. Okay. None of them?

A. None of them.

Q. Okay. And then in ranking, okay, we'll doing ranking now.

I assume because you use the Desara you believe it is the least unsafe?

A. Yes.

Q. Okay. What's next? If it

wasn't around, what would you use next?

A. I probably wouldn't use any. I would probably go to cadaver or do something else.

Q. So the other three, the Coloplast, the Boston Scientific and the TVT®, those SUI sling products, you just wouldn't use them, period, true?

A. Definitely not.

Q. True?

A. Yes.

Q. Are there any studies showing the long-term efficacy and complication of the Uretex or the Caldera Desara sling?

A. No.

Q. If the Uretex sling were still on the market, would you use it?

A. Yes. That would be my preferred sling.

Q. Above the Desara?

A. Yes.

Q. And what happened to it?

A. It was a French company called Sofradim and something happened, it got sold,

and I think Covidien purchased them. BARD didn't purchase them, so they lost the rights to import the sling.

Q. So is that sling still on the market somewhere?

A. I don't think so.

Q. In your opinion about the relative merits of the various slings and instruments and techniques, you're not aware of any medical review or medical literature that makes a comparison like that and reaches those kinds of conclusions, true?

A. True.

Q. Okay. This is all essentially based on your personal opinion based on your personal experience?

A. Yes.

Q. Let's take 2005 to 2010. During that time period, were the IFU warnings any different for the Uretex or the Desara sling versus the TVT® in any material way?

A. 2005?

Q. To 2010, during that time

period?

A. So I was not using Desara.

Q. Well, I thought you said you started in 2010, that's why I included it.

A. Okay. So from -- I started January 2010.

Q. So starting January 2010 and going backward to 2003?

A. Okay.

Q. Which is when you started using the Uretex?

A. Uh-huh.

Q. During that time period, were the warnings in the IFU about the SUI slings any different in a material way between the Uretex IFU, the Desara IFU and the TVT® IFU?

A. With respect to the material?

Q. No, with respect -- by material, I meant relevant or a significant way. Let me reask the question. I'll get rid of the word "material."

A. Okay.

Q. From 2003 to 2010, the warnings in the IFU between the Desara warnings, the

Uretex warnings and the TVT® warnings, were they different in any way that was significant to you during that time period?

A. They were the same, but I want to qualify that I didn't read or look at the Caldera Desara until 2010. So I already knew what the IFU was for the Uretex and the TVT®.

Q. But you looked -- when you looked at it in 2010, did you notice it being significantly different in terms of warnings --

A. It had a lot -- the Desara had a lot more warnings.

Q. Okay. In January 2010?

A. Yes.

Q. Do you know when it came on the market?

A. Around that time.

Q. Okay.

A. I was looking for another sling, they were at a conference and I asked to be evaluated.

Q. So the Uretex and TVT® slings had substantially the same warnings, right,

during the time they were on the market in 2003 to 2010?

A. I think the Uretex had more warnings than the warnings that were in the TVT®.

Q. Okay. During the 2003 to 2010 time period?

A. Yes.

Q. And what was more about them?

A. Injury to organs, talked about retention, talked about urgency. Just more of the routine things that you would expect from a sling.

Q. There was more of that type of warning 2003 to 2010 with the Uretex product than the TVT®?

A. Yes.

Q. Okay. And then the Desara was kind of a new generation sling as of January of 2010?

A. Yes.

Q. And it had more warnings?

A. Yes.

Q. And that was not surprising to

you because there had been many more years of experience?

A. Yes.

Q. Now, in terms of warnings to doctors, manufacturers can get warning information to doctors through methods other than the IFU, true?

A. Yes.

Q. Professional education programs can provide warnings, right?

A. Yes.

Q. There can be surgeon monographs that can supply warnings?

A. Yes.

Q. Have you evaluated any of the sources of warnings that Ethicon gave to doctors other than the IFU?

A. Yes, I've looked at some material.

Q. In your report, do you make reference to any other materials that contained warnings other than the IFU?

A. No. Because essentially information was the same as the IFU, and I

relied on the sure bet that that information was always with the product rather than trying to second guess whether surgeon A, B or C did get this material.

Q. Have you ever reviewed the surgeon monograph with respect to the Prolift® product, which was a Gynemesh® PS product?

Have you evaluated that?

A. What did you call it?

Q. Surgeon monograph.

A. Yes.

Q. You've reviewed it?

A. Yes.

Q. Did that have the same or more or different warnings than the IFU?

A. Had more pictures.

Q. I didn't ask that.

Did it have the same or different warnings than the IFU?

A. Pretty much the same.

Q. Okay. Did you review the professional education materials for the TVT® and the Gynemesh® PS that were used by

Ethicon to help educate doctors?

Did you review those?

A. I reviewed what was available to me.

Q. Were there any different warnings in the professional education materials for the TVT® or the Gynemesh® PS more than in the IFU?

A. No.

Q. But you don't make -- with respect to your warning sections in both the Gynemesh® report and the TVT® report, the only warnings you refer to are warnings that are in the IFU, true?

A. Yes. And I based that on the fact that that was a sure thing for me that that came with the kit.

I don't know whether the surgeons viewed the video, looked at the pamphlets. I am not sure what they had done. But that was a constant.

Q. But in any particular case, you would want to examine all of the information that was available from Ethicon to the

doctors in order to assess the adequacy of the warnings, true?

A. Not if they're the same as the IFU. I think it's the same.

Q. Your belief is that none of the materials had any different warnings in them?

A. Correct.

Q. Okay. Are there any warnings in an IFU for an SUI product that you thought were adequate?

A. When I read it years ago, I thought it was adequate. Reading it today, none of them mention frequency. None of them mention how often these events occur, what the long-term consequences are.

So they're all not adequate.

Q. Okay. So when you read the TVT® IFU back in the early 2000s when you tried out the product, you thought the warnings were adequate at that time?

A. I would have thought so, yes.

Q. Okay. And you now have concluded that none of the IFUs for any of the mesh slings are adequate, true?

A. With everything -- yes, with everything I know today, they are not adequate.

Q. None of them?

A. None of them.

Q. And you're saying this because they don't state frequency?

A. Yes.

Q. Okay. Frequency of what?

A. How often is there a bladder perforation, how often is there an exposure, how much mesh contracture occurs, what are the pore sizes, what happened to the effective pore size. It's a very small percentage of the information that any doc needs to truly understand what he or she is going to offer that patient and how to counsel that patient.

So everything we tell a patient before surgery is based on what our understanding is and our best efforts at explaining those risks and benefits to the patients. So when it's very small, you don't have enough information to truly counsel a

patient effectively.

Q. Today is your counseling of the patient based more on the IFU or on your own personal experience?

A. Both.

Q. Is it based more on one or the other?

A. Probably more on my experience at this point.

Q. Now, you say the IFU doesn't tell frequency.

Do you have an opinion as to what the frequency of exposure is with a TVT®?

A. Yes.

Q. Because I thought -- here's the reason I'm asking this. I thought we went down this before, and I thought you said rather than -- let me back up.

I thought you said before you didn't have an opinion as to what the percentage of frequency was with any of the potential complications, and that's where I'm getting confused. So I'm going to ask that

broad question first.

A. Yes.

Q. Do you have an opinion as to the frequency of any of the potential complications with a TVT®?

A. Two-part answer.

Q. Okay.

A. No, because I don't know the denominator.

Q. Right.

A. And I don't know -- what I know for certain are the patients that present to me with those complications, and the patients that present to other surrounding surgeons with those complications. So the only way to know that is to pool a very large number of docs and figure out what it is. And even if you found out what it was, you would have to know the exact number of slings that went in.

Q. So do you believe that the percentages of any of the complications with the TVT® such as exposure, chronic foreign body reaction, chronic pain with intercourse, do you believe that is knowable?

A. It can be knowable, yes.

Q. Okay. So do you know of anyone or any paper or anything that would give reliable percentages of the frequency of complications such as dyspareunia, contraction, exposure?

A. That study hasn't been done.

Q. Okay. And you're not aware of any published papers on those topics?

A. Correct.

Even the Nilsson paper that's cited on the back of the AUGS, SUFU, had almost a -- half the patients went away. So although they reported a few complications, you don't know what the other 45, 47 patients that got lost to follow-up were doing.

Q. So if a patient asked you, "What is the percentage chance that I'm going to have dyspareunia after a sling procedure," you wouldn't be able to give them a percentage?

A. The percentage I give -- I can give them percentage on what I do. The way I do.

Q. I mean, the general, if they ask you just generally, not just you, Doc, just generally --

A. 25 percent. 25 percent.

Q. -- have dyspareunia?

A. 25 percent can have dyspareunia.

Q. Okay. What's your source for that number?

A. That source is a paper by Hilary Cholhan.

Q. And that's not -- is that long-term dyspareunia or temporary or both?

A. It was de novo dyspareunia.

Q. But long term or --

A. It never got followed up, reported after that.

Q. That's all products, not just TVT®?

A. That was not just specific TVT®.

Q. Is that what you tell patients then, that there's a 25 percent chance of dyspareunia with a general percentage with

mesh?

A. No. Because I don't follow the manufacturer's instructions for placement.

Q. What if they ask you what the general percentages of exposure or erosion, do you give a percentage?

A. It's from 4 to 12. 4, 18, 17 percent. It depends on --

Q. I'm getting confused because a minute ago I asked you if there were any published studies about these percentages, and you said no, and now you're rattling off. I'm having trouble.

A. There are some papers that talk about, but they're very small groups and the percentages are all over the board.

Q. So I think I used the word "reliable," and I think that's -- so you're not aware of any reliable scientific papers that have been published that give what you think are reliable estimates of the percentage of complications of dyspareunia, pelvic pain, erosion, contraction, that type of thing, true?

A. True.

Q. You said that you gave the general numbers like 85 percent cure and 7 or 8 percent improvement with mesh slings.

Remember that?

A. That was with the TVT®.

Q. TVT®.

Are there any general numbers like that for other products?

A. Yes.

Q. What are they?

A. I know the Mersilene sling by Steve Young had a 94 percent success rate.

Q. Okay.

A. Studies cite fascial slings 95 percent.

Q. I was talking about polyester slings.

Are there any results on the Desara sling, the Uretex and the other ones that you've mentioned?

MR. MATTHEWS: Object to the form. Those are not polyester slings.

MR. BALL: Polypropylene. That

was my error.

MR. MATTHEWS: Okay.

QUESTIONS BY MR. BALL:

Q. Polypropylene slings, the other ones, is there any data that you find reliable about the success rates with other polypropylene slings?

A. There's data to suggest that all slings have a high cure rate.

Q. Of?

A. 85, 90. Depending whether you look at objective or subjective data, sometimes that a little bit different.

Q. So in terms of success rates, the TVT® sling is consistent with the other polypropylene slings that have been on the market the last 10 or 15 years, true?

A. Yes.

Q. Okay. And in terms of complications, you don't have reliable data to compare the rate of complications with TVT® versus the other polypropylene slings that have been on the market the last 10 or 15 years, true?

A. True.
Q. I wanted to ask you before we get into the Prolift® here, can you tell me --
MR. BALL: Let's go off the record for a second.
(Off the record at 11:52 a.m.)
QUESTIONS BY MR. BALL:
Q. Are you aware of any published scientific literature that is critical of the instruments used with TVT®?
A. No.
Q. Are you aware of any published scientific papers that are critical with the technique recommended in the IFU for the TVT®?
A. No.
Q. Are you aware of any scientific papers that are critical of the mesh design with the TVT®?
A. No.
Q. Okay. Have you read -- do you know which versions of the IFU -- well, let me back up.

Have you read the IFU that accompanies TVT® today?

A. I don't think so.

Q. Okay. So you don't have any opinion as to whether it's adequate or not, the warnings in there?

A. No, I actually tried to click on it several times and it didn't download for me to get the latest version.

Q. Other than being a doctor who reads warnings, do you have any other qualifications in the content of warnings?

A. I'm not sure I understand the question.

Q. What are your qualifications to judge the adequacy of warnings besides the fact that you're a doctor that reads IFUs?

A. I've written several instructions for use on instruments I've designed.

Q. For what?

A. One was for a vaginal dilator for women that have a shortened vagina.

Another one is for an

instrument to do pelvic surgery, sacrospinous colpopexy.

Q. Have those been commercialized, those products?

A. Yes.

Q. And did you write the warnings in the IFU?

A. Yes.

Q. Or just the technique?

A. I wrote both.

Q. Okay. Did anyone help you write the warnings?

A. They gave me a handout on what it should include, and I wrote it.

Q. If I wanted to have those IFUs, where would I get them?

A. I don't know where you would get them at this time. Here's why: The company got sold. Currently the product got bought by -- let me think. I'll think of it in a second. I'll think of it.

So I did not have a binding contract with the company that I did this for so when they sold it to -- oh, I'll think of

the name. Who are they?

So I don't get any royalties or anything on that. I don't know where it's at.

Q. Do you have copies of the IFUs for those products?

A. I'm sure I don't.

Q. Do you still use the products?

A. I do not.

Q. So you don't have any copies of IFUs that you've ever been involved in writing?

A. That's correct.

Q. In addition to the IFU, doctors -- in addition to the IFU and other materials the company might supply to doctors about warnings, the doctors also have a responsibility to keep up on continuing medical education about the procedures they perform, true?

A. Sure, yes.

Q. And they also have a responsibility to be aware, for example, of FDA notifications about the procedures they

use, true?

A. Yes.

Q. And also the position statements and publications of the organizations they're members of, true?

A. Yes.

Q. And those can all be sources of information about warnings, true?

A. Yes.

Q. Are there more cites in your reports to company documents or peer-reviewed literature?

A. Probably company documents.

Q. Why is that?

A. I thought that that was a very relevant source of things that were not in the peer-reviewed literature that truly spoke to the issues that the mesh had that were not evident by any peer-reviewed literature.

Q. One reason I want to cover before we get into the Gynemesh® is I want to make sure that I understand and have on the record any communications that you recall having with anybody who worked for Ethicon.

Okay?

A. Okay.

Q. All right. So, first of all, I think you said back in the early 2000s there was a person who encouraging you to try TVT®, right, and you gave us a name earlier in the deposition, and it escapes me?

A. Hattie Loggie.

Q. Okay. Other than her encouraging you to try TVT® in your SUI surgery and you telling her that you had some issues with it, anything else you remember about those communications?

A. With her?

Q. Yes.

A. No, I remember there was -- I had communications with her.

Q. I'm going to get to other people in a minute. I want to take them one at a time.

A. I am sorry, ask that question again.

Q. So you had communications back in the early 2000s with this woman about --

where she was encouraging you to try TVT®, and you tried it, and you told her what your issues were, right?

A. Yes.

Q. Anything else about those communications that you can recall?

A. No. Nice lady. She wanted me to try it, and I declined.

Q. Well, you tried it and then declined using it more?

A. Right. Yes.

Q. By the way, did the two people you tried it on have any long-term problems, do you know?

A. No, I don't think so.

Q. And then you also mentioned a Will Irby at one point in time that you had a conversation with.

A. Yes.

Q. Who was he?

A. I don't recall his exact title, but he had something to do with maybe the product manager for TVT®.

Q. Okay. And what were the nature

of your communications with him?

A. He was introduced to me by Hattie Loggie as someone who might be a potential customer for using TVT®.

Q. Okay. And what was the nature -- and then just tell me about those communications.

A. My recollection is I met the man once. It was in my office. I asked about the product. He gave me a VCR at the time --

Q. Was this before or after you tried it with --

A. It was before.

Q. Before?

A. Yeah, it was before.

Q. So this was kind of in conjunction with you trying it out the first time?

A. Yeah. Yes.

Q. Okay. Anybody else from Ethicon that you ever had any communications with about TVT®?

A. Retropubic TVT®?

Q. Yes.

A. Now, there was a Jim Bly, but I think that was regarding TVT-Secur. So I think retropubic TVT® was Will Irby. There was Hattie Loggie. There was maybe her regional manager, Hattie's regional manager, that moved to Atlanta, but I can't recall his name.

Q. And that was all about wanting you to try it out, and you tried it out, and you told them your thoughts?

A. Yes.

And after I tried it, I think Hattie set up this meeting. I remember they -- we went to dinner at Morton's and he asked me what my concerns were, and I relayed then my concerns about the tunneling, the curling, the rolling, the fraying, all of those things.

Q. Now, did you get any specific training on using the TVT® before you tried it out?

A. Yes.

Q. What was the nature of that

training?

A. I think there was some sort of course. I remember being flown. I don't remember where I flew, maybe it was Cincinnati. And there was a -- it was pretty impressive. There were a couple hundred people there. They took us in in buses, and they had live surgery, video and --

Q. This is about TVT®?

A. Yes.

Q. And this was before you tried it the first time?

A. Yes.

Q. Did you ever go locally here and watch anybody or have any training from that?

A. No.

Q. Did you ever go over to France with Prolift®?

A. No.

Q. Or Gynemesh®?

A. No.

Q. Now, I've been talking about TVT®. Now I want to switch to Prolift® or

Gynemesh®.

A. Okay.

Q. Prolapse products.

A. Okay.

MR. MATTHEWS: Well, he didn't give an opinion on Prolift®.

MR. BALL: He gave an opinion about Gynemesh®.

MR. MATTHEWS: Right. That's two different things.

MR. BALL: Yeah, I understand. But his report is full of references to Prolift®. Okay.

QUESTIONS BY MR. BALL:

Q. Is Prolift® made out of Gynemesh® PS?

A. It is.

Q. All right. And did you ever have any communications with anybody from Ethicon connected with any product made out of Gynemesh® PS?

A. So let me just think out loud for a second.

Okay?

There was a young lady that drove me to Wichita, Kansas, to watch Dave Robinson, Dr. Robinson, who I had met a couple years prior, so I think worked for Ethicon. I recently just took out one of his posterior Prolift®s just a few days ago. So Dave Robinson. I don't recall the girl's name. Maybe Tracy. We went -- she drove me in her car, went to Wichita, Kansas, if I recall correctly, her, Dr. Robinson.

Q. Dr. Robinson did the surgery?

A. Yes.

Q. Okay. And you watched him do it?

A. I watched him do it.

Q. Okay. That's one episode.

At that time had you used Gynemesh® PS any?

A. I had not.

Q. Okay. Any other communications you had with anybody from Ethicon about any Gynemesh® PS product?

A. I'm thinking. I don't recall. If you have something to jog my memory.

Q. What happened at the end of that Wichita trip?

A. Like typically what happens, they want you to become a customer, try the product. It seemed like Dr. Robinson put it in pretty smooth. It seemed smooth. He talked about what the advantages, disadvantages were. I was very comfortable doing vaginal surgery, doing sacrospinous. And my interactions with Dave, a couple years before he was interested in that instrument that I developed for doing sacrospinous and accessing that area of the pelvic floor and that -- really don't think I have any other recollection besides that.

Anybody else? I think Jim Bly, maybe Jim Bly brought me. I always like to have stuff. I always like to play with it, touch it, read things, look at the trocars. I'm very hands-on, mechanical.

Q. What's Jim Bly's role?

A. He's a salesperson.

Q. But you think that was about the TVT-O or about the --

A. No.

Q. -- or the Secur?

A. He was about Prolift® and Secur.

Q. Okay. And you think you did have some interaction with him about a Gynemesh® PS product Prolift®?

A. It was about a posterior Prolift®. I still have it.

No. No, it was a total Prolift®. It was a total.

Q. And what was that communication about?

A. Basically wanting me to try it.

Q. Okay. So any other communications?

A. Jogging my memory, that's all I remember.

Q. Okay. Do you know if there's any difference between the mesh that is Gynemesh® PS and the mesh used in TVT®?

A. Yes, there is.

Q. What's the difference?

A. Well, PS is 45 grams per meter

squared. It has --

Q. So it's lighter?

A. It's lighter, which is why TVT® is considered heavy. And learning all of this and thinking about it, reading about it and everybody's in a lightweight mesh, you think that someone would make a sling that's lightweight. The pores have a funny configuration. They're not the same. They vary in size, and there's a fiber that runs across it. So depending on how you measure it, you can get something from very small to 1 millimeter to 1.5 to .3. It's all over.

Q. Are the TVT® pore sizes that consistent?

A. Before you implant it, yes.

Q. So far the differences between TVT® and Gynemesh® PS is irregularity in pore size and also the weight.

Anything else?

A. They're both polypropylene.

Q. Is the polypropylene the same, to your knowledge?

A. Yes.

Q. Okay.

A. They're both polypropylene. The TVT®'s used for slings. The Gynemesh® is used for prolapse, cystocele, rectocele, vaginal apex support. Variable size in the pores. Color's different. It's got blue stripes in the Gynemesh® where the early TVT® was clear. Later TVT® is blue.

Q. Is Gynemesh® PS a lightweight, macroporous, monofilament mesh?

A. It's medium weight, macroporous, monofilament.

Q. What's the dividing line between light and medium --

A. About 28, 28 -- I am sorry.

Q. We've been doing great.

A. Sorry.

Q. Lightweight cutoff is what? What were you just going to say?

A. 28 to 30 grams per meter squared.

Q. And below, that's lightweight?

A. Yes.

Q. And 30 to what is medium

weight?

A. 60, 50.

Q. And above 50 or 60 is heavyweight in your view?

A. Yes.

Q. I'm now going to be asking you principally about Gynemesh® PS, okay, so we're switching gears. It doesn't mean that there might not be some overlap, but we're switching gears.

Doctor, can you tell me -- first of all, have you ever used Gynemesh® PS?

A. Yes.

Q. Okay. Kind of globally tell me what your experience is using that, and then I'll ask you more specific questions.

A. I didn't like it.

Q. Well, I didn't ask whether you liked it or not yet. I kind of figured you didn't like it or you wouldn't be here.

What have you used Gynemesh® PS for?

A. I've never used Gynemesh® PS.

I've used Prolift®, which has Gynemesh® PS.

Q. But I'm encompassing -- so what what have you used -- let me back up.

Gynemesh® PS -- Prolift® is made out of Gynemesh® PS, right?

A. Yes.

Q. All right. The only Gynemesh® PS you've used is Prolift®?

A. Yes.

Q. Okay. And how many times have you used Prolift®?

A. Just once.

Q. Okay. And when was that?

A. Shortly after I visited Dave Robinson.

Q. Okay. Did that patient have complications?

A. Yes.

Q. Okay. In what nature?

A. She had protracted pain.

Q. Did it eventually go away?

A. She didn't come back.

Q. So you don't know?

A. Don't know.

Q. All right. Just remembered. When you do an implant of a TVT® -- or excuse me, an explant of a TVT®, the surgeries that come to you, what has been your success rate in resolving their problems?

A. A percentage, you're looking for a percentage?

Q. Yes.

A. 95 percent.

Q. Okay. And when you do that, do you do something else to deal with their stress urinary incontinence?

A. Not at that time.

Q. Okay. You take out the sling and kind of see how they do, is that the idea?

A. Yes.

Q. And sometimes you have to, what, put in another sling or do some other kind of procedure?

A. Yes.

Q. What percentage of the time that you've taken out a TVT® do you have to do some other kind of procedure?

A. It's a great question. About half the time.

Q. About half the time.

And then the other half, you take it out and they're okay?

A. They're fine. They're leaking a very small amount due to the scarring from all the surgery and with the experience they had, they would rather leak a little bit at that point rather than do anything else at all.

Q. And when you do the other half of the time when you do a repeat surgery for SUI, what kind of surgery do you do?

A. I offer them everything as I mentioned above. Because --

Q. Just as if they're a new patient, so to speak?

A. And they are sort of a new patient because I don't do partial removals. I do complete removals so the entire pelvis is sort of naïve except with scarring from multiple surgeries. But it gets her back to a starting point.

Q. Okay. And you've been able -- when you do these explant surgeries for TVT®, you've been able to remove all of the mesh?

A. Yes.

Q. All right. Now, so you tried Prolift® one time.

Why did you not like it?

A. I instantly saw the curling similar to what would happen with a TVT® because, again, the same concept.

Q. The curling of the arms?

A. The curling of the arms going through and the pulling and the fraying, and you can actually see the tissue get pulled -- as you're pulling on the arm to tension it, you can actually see the rectal tissue pulling in with it. I regret not removing it right then and there.

Q. On the one person?

A. On that one person.

Q. All right. So how many Gynemesh® PS products have you explanted?

A. Does that include Prolift®?

Q. Is that a Gynemesh® PS product?

A. Okay. Yes.
Q. Okay.
A. In 2015?
Q. No -- well, we'll start there.
A. I know that number specifically.
Q. Okay. Sure.
A. About 30.
Q. Okay. And were those all Prolift®?
A. Yes.
There's some Gynemesh® also. Piece Gynemesh®.
Q. That was cut from a sheet?
A. Yes.
Q. All right. So how many of each of those?
A. About seven Gynemesh® from a square piece, auto made.
Q. In other words, a surgeon cuts it?
A. Yes.
Q. And through your career, how many Gynemesh® PS products have you

explanted?

A. So including everything with Prolift®?

90.

Q. And how many of those have been Prolift® versus surgeon-cut Gynemesh® PS?

A. Surgeon-cut, 15.

Q. Now, with respect to Gynemesh® PS, which is what your report is about here, okay, so that's about the mesh, right?

A. Okay.

Q. You're addressing the mesh that's cut by the surgeon and can be used for prolapse, true?

A. Okay.

Q. Right, that's what your report addresses?

A. Yes.

Q. Just so we're clear. Exhibit 3 is a reported that's entitled "Gynemesh® PS," and that is addressing the mesh that can be cut from a sheet and used to -- in various surgeries, correct?

A. Yes. Just to be clear when we

talk, are we adding Prolift®, or are we sticking to just the sheet? I'm a little confused.

Q. If I have a Prolift® question, I'll ask you about it.

A. Okay.

Q. But I'm talking now about Gynemesh® PS, okay. The mesh itself, do you believe that that was so unsafe it never should have been sold?

A. Yes.

Q. Okay. Why is that?

A. It folds and curls because of its poor design. It bunches and rolls when it's placed. The vagina is not the anterior abdominal wall. And this mesh was designed for the anterior abdominal wall. And in the anterior abdominal wall the surgeon can lay it nice and flat. That's not the case in the vagina. The vagina is a tubular structure and the attachment points create oblique stress when you try to secure it. And then the vagina moves very differently. It has completely different tensile characteristic

requirements than the anterior abdominal wall.

It's really a product that should have never been put in the vagina.

Q. Mesh in general?

A. Yes.

Q. All right. Not just Gynemesh®?

A. Mesh in general.

Q. So I want to make clear on that.

It's your opinion that mesh in general should not -- of any kind should be used for treatment of prolapse, true?

A. Vaginally placed.

Q. Vaginally placed?

A. Because there is no mesh that's designed specifically for the mechanical requirements of the vagina.

Q. Okay. In your view, is Gynemesh® PS the same as the mesh used for hernia repair?

A. Yes.

Q. Okay. No differences?

A. No.

Q. So were there companies besides Ethicon that made mesh for use with prolapse repair?

A. Yes.

Q. Have you used any of their products?

A. Have not.

Q. Okay. But you don't believe any product ever made, any mesh product ever made, for vaginal repair of prolapse is safe?

A. That is correct.

Q. Now, are there any mesh products on the market today for vaginal repair of prolapse?

A. Placed vaginally?

May I ask a question? Placed vaginally?

Q. That's what I meant.

A. There are products that are available at the surgeon's discretion to place in the vagina.

Q. What are those?

A. There's a Boston Scientific product Polyform.

Q. Have you ever used it?
A. No.
Q. Okay. And you believe it's unsafe, too?
A. Yes.
Q. And is that -- any others?
Any other products?
A. I was thinking. So there's Gynemesh®, there's Boston Scientific, there's Coloplast has Restorelle. Let me see who the players are. So Boston Scientific Polyform, Ethicon Gynemesh®, and Coloplast Restorelle. I think that's it.
Q. Do you know surgeons today that use polypropylene mesh for vaginally -- what was the word you used? Vaginal entrance or whatever?
A. What did I use, support? I'm not sure what I used.
Q. For vaginal prolapse repair, going through the vagina, not abdominally, do you know surgeons today that use mesh for that type of surgery?
A. So I want to answer the

question. I know there's people using it, yes.

Q. Okay.

A. I don't know them personally, but I know they're using it.

Q. So I want to make sure I understand your opinion as to why Gynemesh® is unsafe and should never have been sold.

One opinion I'm hearing is that mesh in general is just not compatible with use in the vagina, true?

A. Correct.

Q. Okay. Any other specific criticisms you have of Gynemesh® PS from a design standpoint?

A. It's heavier, stronger than it needs to be placed in the vagina. Even though it is sort of medium weight, macroporous, monofilament with pore sizes that in certain areas are above a millimeter, in other areas they're not, which enhances bridging fibrosis and scarring. The vagina is just not an organ -- the vagina doesn't have an organ that's conducive for placing

mesh. Let's see if I wrote anything else.

And obviously all the things we mentioned about polypropylene and the chronic inflammation and the scarring, especially in a vagina, because the vagina shrinks differently than the anterior abdominal wall. The anterior abdominal wall shrinks in the plane of which the mesh is placed.

Q. You mean when you're doing a sling?

A. Well, when you're -- let me back up.

Q. Okay.

A. I meant the abdominal wall, when Gynemesh® is placed in the abdominal wall. It's in a sheet.

Q. Okay.

A. But when it's placed in the vagina, it's curvilinear. So just like scar will shrink a little bit, it will shrink in a way that will make the vagina not functional.

Q. Does the mesh actually shrink, or is the contraction connected with the formation of scar tissue?

A. The whole unit shrinks. It's a combination of the bridging fibrosis, even scar without mesh is going to shrink. But if you add chronic inflammation to it and you add an attachment point and it pulls together, it's going to shrink. It's not that the -- it's not that the fiber in the mesh shrinks. It's not like the polypropylene itself is going to shrink. But the gaps between the polypropylene shrink.

Q. That's part of the scarring process?

A. And the bridging fibrosis from chronic inflammation.

MR. MATTHEWS: When you get to a break point.

MR. BALL: Sure, we can do that right now.

(Off the record at 12:22 p.m.)

QUESTIONS BY MR. BALL:

Q. Doctor, the Nilsson paper from 2013 that we referred to earlier concluded the TVT® operation is durable for 17 years with a high satisfaction rate and no serious

long-term, tape-induced adverse effects.

You're aware of that conclusion, right?

A. Yes.

Q. All right. And you did not cite that paper in your report concerning TVT®, correct?

A. Yes.

Q. All right. And why did you not cite that paper?

A. The paper started with 90 patients, ended up with 45.

Q. Followed over 17 years?

A. But it's half the population. So what if the other half had a problem. Actually I did some calculations and some of the percentages that he mentions in there are not accurate. He's using -- he's not using -- the 90, he's using less than 90, and it ends up being a higher percentage than what it should be.

So I had some issues about the paper, and the calculations were off. Half the patients were gone. It wasn't -- the

paper would be much more meaningful if 95 percent of the patients were there followed up.

Q. But you don't have any papers cited in your report about TVT® that reached a contrary conclusion that TVT® had a low satisfaction rate with serious long-term, taper-induced adverse effects?

Do you have any of that -- any papers to that effect cited in your report, true?

A. Would you repeat that last sentence?

Q. You don't have any papers cited in your report that says TVT® does not have a satisfaction rate and has serious long-term, adverse effects?

A. No.

Q. True?

A. True.

Q. Do you have in your report cited the Svenningsen from 2013 that concludes long-term objective and subjective outcome after retropubic TVT® is excellent

with a low number of reoperations, even in a nonselected cohort of patients?

Do you have that paper?

A. I would have to look.

Can I see the paper?

Q. Just asking if you have it cited in your report.

A. No, I don't.

Q. Okay. Why not?

A. I tried to cite every paper that I could get my hands on, look at everything that was available to me. There's thousands and thousands of papers on TVT® and slings and et cetera.

Q. You don't cite a single paper in your report that gives favorable findings with respect to TVT®, true?

A. No, I do. I mentioned the Thomas trial, and it says that in the short term, these patients have good outcomes.

Now, how many papers do you really need to cite in there that in the short term the sling works?

Q. Yeah, let me ask you this: You

don't have any papers that give favorable outcomes for long-term studies on TVT®, true?

A. There's not a good, long-term study to cite.

Q. Well, this one says long term -- this Svenningsen paper is termed long-term follow-up of the retropubic TVT® procedure, and you did not -- were not familiar with it and did not cite it, true?

A. Can I see it again?

Q. Well, I'm just asking you if you cited it in your paper, in your report.

A. I didn't cite it.

Q. And then there's another paper by Serati, et al., "Tension-Free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at a Ten-Year Follow-Up."

Did you cite that paper in your report?

A. I don't think so.

Q. Okay. And it concludes the ten-year results of this study seem to demonstrate that TVT® is a highly effective

option for the treatment of female SUI recording a very high cure rate with low complications after a ten-year follow-up?

You're not aware of that conclusion?

A. Many times --

Q. Are you aware of that conclusion?

A. No.

Many times TVT® doesn't really mean Ethicon TVT®; it's a generic term that talks about slings in general.

Q. Well, this one says it was Ethicon.

A. Okay.

Q. But you're not familiar with the study?

A. No.

Q. And you did not cite it in your report?

A. Correct.

Q. And, in fact, did you make a specific search to see if you could find studies about the long-term efficacy and

concerns related to TVT®, did you make that search in connection with your report?

A. Yes, I did.

Q. And you found the Nilsson paper or were familiar with the Nilsson paper?

A. Yes.

Q. And decided not to mention it in your report?

A. Yes.

Q. And you did not find the Serati or the Svenningsen paper?

A. Correct.

MR. MATTHEWS: Do you have an extra copy of those that I can look at? If you don't mind.

MR. BALL: I don't mind.

QUESTIONS BY MR. BALL:

Q. With respect to Gynemesh® PS, did you make a search for any papers regarding multi-year follow-up with respect to use of Gynemesh® PS products in women for prolapse?

A. Yes.

Q. Okay. Do you have the

Jacquetin 2013 paper cited in your Gynemesh® report?

A. Let me take a look.

Doesn't look like that I do.

Q. Do you have the -- so you're not aware of the conclusion from that report, in that study?

A. No.

Q. Do you have cited in your paper the Landesherr 2012 publication paper, study, surgical intervention after transvaginal Prolift® mesh repair, retrospective single-center study including 524 patients with three years median follow-up.

Did you have that study cited in your --

A. I excluded studies that had Prolift® because I was not writing a report on Prolift®.

Q. Well, isn't Prolift® made from Gynemesh® PS?

A. There's a world of difference between Prolift® and Gynemesh® PS.

Q. Excuse me, is Prolift® made

from Gynemesh® PS?

A. Yes.

Q. Do you cite multiple internal company documents referring to Prolift®?

A. Yes.

Q. And yet you don't cite any independent literature relating to Prolift®, true?

A. That's correct. Because --

MR. MATTHEWS: Well, let me finish his answer.

THE WITNESS: Because there's a world of difference between adding arms that extend into the levators and the forces exerted that are on that mesh as opposed to a small piece that doesn't have arms exerted.

QUESTIONS BY MR. BALL:

Q. So why did you cite numerous internal documents and testimony concerning -- in fact, you cited studies, the clinical study reports.

Those were Prolift® devices, weren't they?

A. Yes.

Q. Okay. You cited those. You gave percentages and everything in your report, right?

A. I --

Q. Excuse me, didn't you do that?

A. Yes.

Q. But you did not cite a single piece of published literature relating to Prolift®, true?

A. Correct.

Q. And do you think that's scientifically appropriate to cherry-pick on what Prolift® documents and literature you use?

Is that scientifically appropriate?

MR. MATTHEWS: Objection to the form.

QUESTIONS BY MR. BALL:

Q. I'll withdraw the question and ask it this way.

Do you think it's scientifically appropriate to include in your

report numerous references to Prolift® from internal documents and clinical study reports and not refer to any Prolift® literature?

A. Yes.

Q. Okay.

A. And the reason for that is I was looking at the material, not the way the material works in the body with arms.

You cannot take a small piece of mesh and place it between the vagina and the bladder without arms and have that same clinical consequence with arms.

Q. Well, then why did you put all of the Prolift® study results and all the Prolift® references to internal documents, why did you put those in your report?

See, I understand that Gynemesh® PS cut from a sheet, you believe, is different than Prolift®. I understand that.

But how come you put in some Prolift® documents and didn't put in any Prolift® literature? That's what I don't understand.

A. Because there's a difference between the clinical execution of putting in Prolift® with arms that extend into the levators as opposed to putting in a small piece of Gynemesh®.

Q. Didn't you refer extensively to results where Prolift® with arms were put in?

Look at page 21.

A. Yes.

Q. You have extensive discussion of Prolift® -- of a Gynemesh® PS product with arms, the Prolift® product, put in. You have extensive discussion of that at page 21, don't you, sir?

A. Yes.

Q. And it goes on over, you have a more extensive discussion at page 22, correct?

My only point, Doctor, is that pages 21 and 22, at least, you have extensive discussions of studies done installing Prolift® in women, implanting Prolift® in women, true?

A. And I used those from the point

of view of shrinkage of the material.

Q. Those paragraphs don't say, "The only reason I'm citing this is about shrinkage." You start off saying, "An Ethicon clinical study for pelvic prolapse repair involving the Prolift® showed serious" --

A. A transvaginal Gynemesh® for pelvic organ prolapse repair demonstrated to Ethicon that the mesh was not effective prolapse treatment according to Ethicon's own criteria.

Q. "This study, which performed by physicians who helped develop the Prolift® device," right?

A. Yes.

Q. And it's all about the Prolift®, isn't it?

A. No, it says that they helped develop the Prolift® device.

Q. Is this data placed upon a Gynemesh® used in a Prolift® device with arms, the data at pages 21 and 22 of your report?

A. I believe so.

Q. Okay. Did you make in your -- in your evaluation in this case, did you consider to some degree internal documents and internal data related to Prolift® devices made out of Gynemesh® PS?

A. I considered everything that was available.

Q. Including that?

A. Yes.

Q. Did you make any search for literature about these long-term success rates of Gynemesh® PS when used in Prolift® devices?

Did you make that search?

A. Yes.

Q. And did you find these three papers that I have -- in your search these three papers that I mentioned?

A. I did not find those.

Q. Now, in the --

MR. MATTHEWS: Well, I am sorry. Three papers that you mentioned?

MR. BALL: Jacquetin, Landesherr --

MR. MATTHEWS: Okay.

MR. BALL: I didn't quite get to the third one. The Altman paper is also not mentioned there.

QUESTIONS BY MR. BALL:

Q. The one-year follow-up, you didn't mention that one in your report, did you, sir?

A. No.

MR. BALL: Your point is well taken. I had forgotten the Altman paper.

QUESTIONS BY MR. BALL:

Q. Now, Doctor, when you removed Gynemesh® PS, whether Prolift® or non-Prolift®, when you removed Gynemesh® PS in these explant surgeries you do, what is your success rate there?

A. How are we defining success rate?

Q. Well, how would you define it?

A. Well, there's two aspects: One

is how much do you remove, and two, how are the patients doing.

Q. Okay. So give me the results under both of them.

A. If it's a Prolift® that hasn't been revised or manipulated in the office, I can usually get out the vast -- all of the mesh between the rectum and the vagina.

The arms, depending how they're placed, because there's variable there. For example, in the one I just took out a few days ago from my friend Dave Robinson, I removed the woman's entire right arm out of the gluteus muscles. On her left side, I removed half the arm. Almost invariably these patients are pain free after surgery. Not 100 percent. And you can't get 100 percent of the mesh out.

You can get more of the Prolift® out posteriorly. The anterior Prolift® you can, again, remove most of the mesh from between the vagina and the bladder. The arms that go around the descending pubic ramus, they're very hard to get. About

50 percent of the time you can remove the distal arm and about 20 percent of the time you can remove the entire apical arm.

If it's a total Prolift® and that bridge of mesh between the anterior and posterior have combined together, it is a big, wadded, folded, scarred, difficult nightmare.

Q. So let's take the women having success from a quality of life and pain standpoint.

What is your percentage of success with explant surgery on Gynemesh® products?

A. Could you ask the question again differently?

Q. Yeah.

With respect to women from becoming an improvement in quality of life and not having ongoing problems using -- defining that as success, what is your success rate with explanting Gynemesh® products?

A. So they have an improved

quality of life. They don't have the quality of life that they had before because they've been through whatever they've been through.

So the way I can answer the question is improved quality of life with pain reduction, about 80 percent of the patients have no pain. The other 20 percent have some degree of pain.

They still have their prolapse. Their prolapse comes back. For the posterior.

For the anterior, it's a little bit less because there's more arms.

Q. A little bit less what?

A. Improvement. 70 to 75 percent.

Q. Have pain go away?

A. The pain goes away.

The other 25 percent still have some pain. 7 percent of the women have a scarred, narrowed, foreshortened vagina, and there's all kinds of variations of residual prolapse that occurs.

Q. When you do the explant procedure, do you have to deal with the

recurrent prolapse?

A. Not at that moment. You can't. The dissection is extensive to remove it.

Q. On most of the patients you see, do they need a follow-up surgery for recurrent prolapse?

A. Yes.

Q. Okay. Is that usually performed by you or someone else?

A. If they return, I'll do it. But they don't all come back.

Q. The great majority of the patients need -- after the mesh is removed, still need treatment for prolapse, surgical treatment?

A. Some. I don't have an exact number. These patients live many states away, and they're seeking my services for removing the mesh and then they may go somewhere else.

Q. But your estimate would be the great majority of them will need treatment for recurrent prolapse?

A. The great majority of them have

prolapse. I don't know if they'll seek treatment.

Q. Prolapse of grade 2 or greater?

A. One segment, two segments, some, yes.

Q. So let's get away from the explant now and just talk to women that come to you needing surgical treatment for prolapse.

All right. What alternatives do you offer them?

A. Well, if they need an A and P repair, cystocele, rectocele, I just use native tissue.

If they need an apical procedure, I will use polypropylene or suture.

Q. So if they need a posterior, anterior repair, you'll use what?

A. Just native tissue. Absorbable sutures.

Q. And if they need an apical repair, is that an abdominal procedure?

A. Yes.

Q. And you'll use mesh with that?
A. Yes.
Q. And what kind of mesh?
A. I use BARD Alyte.
Q. How does that differ from Gynemesh® PS?
A. The grams per meter squared of Gynemesh® is 45. The grams per meter squared for the vaginal arms of the Alyte is 17. So it's very light. And that's less -- that's about a third of the weight. The pores are much larger. The filaments are much smaller, and even there, I still sew the graft apart to increase the pore size.
Q. And what is the size of the mesh, once you -- is this cut from a sheet, the stuff you use for the ASC?
A. Yes.
Q. This is for an abdominal --
A. Yes.
Q. -- sacrocolpopexy, right?
A. Yes.
Q. And what is the size that you cut it from the sheet?

A. I think that's a good question.

Q. You've only said that twice today. I hope I have asked more than two good questions.

A. So the vast majority of surgeons will do a sacrocolpopexy and tunnel between the vagina and the rectum abdominally. That's still placing the mesh vaginally. They may think there's an advantage because there's no incision. That's not been my experience. Those women still have problems because of placing that mesh that way.

So what I do is I limit the mesh to the apex. So the lancing had three levels: Apex, middle vagina, and distal vagina. So a TVT® is on the distal anterior segment, and the sacrocolpopexy is on the apex. I only place 2 centimeters on each side of the Y. So in total, I place 4 centimeters of mesh by 3 centimeters. So a very, very small piece.

Q. So it's two pieces that are 2 centimeters by 3 centimeters?

A. No.
Q. Okay. I'm sorry.
A. It's a Y and at the crux of the Y is 2 centimeters. So if you laid it open, it's 4 centimeters by at the middle part 3 centimeters, and it's actually a circle.
Q. So it's a circle of mesh?
I'm just trying to get the piece of mesh that you cut out before you put it in, how big that?
A. It's very, very small.
Q. How big?
A. It's a circle that has a diameter of 3 centimeters.
Q. Okay. All right. So not all ASCs are done abdominally, is that what I just heard you say?
A. No, all ASCs are done abdominally. They don't all use mesh.
Q. Okay. You're talking about not all apical repairs are done abdominally?
A. Yes.
Q. Okay. What is the recognized in the medical community success rate for

native tissue repairs for anterior prolapse?

A. Would you ask the question again?

Q. Yeah.

What in the medical community in your opinion is recognized as the success rate for anterior prolapse when you use native tissue repairs?

A. What's quoted is 70 percent success.

Q. Okay. What do you tell patients?

A. I tell them the reason there's only 70 percent success is they have other defects that didn't get fixed. So the patient returns with prolapse because rarely do you have -- and there is a paper out there that says there's no such thing as a cystocele, that all cystoceles have an apical component. So if you're only fixing the cystocele, you're going to get an apical component.

Now, the Altman paper does say that if you put mesh anteriorly on a

cystocele, it does better if you do native tissue. However, how many of those patients really would have done well with a native tissue repair with an apical component. The reason --

Q. You mean a native tissue apical component as well as the anterior?

A. Yes.

Q. Okay.

A. So that is well-documented that there are patients that have a cystocele, but really it's a displacement cystocele, and it's displaced because the top of the vagina is coming down as opposed to a distension.

So on a distension, sure, you could do a native tissue repair and you're going to get a much higher success rate than if you have a displacement cystocele. If you have a displacement cystocele, if you don't do an apical component with the anterior repair, you're absolutely going to have a recurrence. So then that's counted as a recurrence of the cystocele.

So that 70 percent success

really is skewed because there's not a single paper in the literature, not one, that looks at outcomes of native tissue that addresses the anterior, the apex, the enterocele, the rectocele, and the perineum. Not a single paper.

Q. So if someone repairs an anterior prolapse and repairs the apical at the same time, do you have an opinion as to what the success rate is?

A. Of the anterior and the apical, yes. If it's a good repair and it holds, it shouldn't come back.

Q. No, what is the recurrence rate, I should say?

A. I'm not sure I understand the question.

Q. In the medical community if you do an anterior prolapse repair and at the same time do a repair apically with native tissue, is there a recognized recurrence rate for that?

A. Yes.

Q. What is that?

A. It's 10 percent maybe.

Q. Okay. So if I'm understanding what you're saying is the reason that there -- and you know there's numbers lower than 70 percent reported in the literature for native tissue repair recurrence, right?

A. Yes, but I answered the question truthfully on what I thought was --

Q. No, I'm not quarrelling with you.

The 30 percent recurrence rate with anterior repair, you're saying that is largely caused because an apical repair isn't done at the same time?

A. Because the patient had a combined defect, only one got fixed.

Q. Now, how about posterior repair, what is the recognized recurrence rate on a posterior repair, native tissue?

A. 15 to 20 percent.

Q. Is that affected at all by doing the apical at the same time?

A. Oh, yes.

Q. Same deal?

A. And the perineum.

Q. Now, you said -- is the only alternative you talk with patients about is native tissue repair?

A. For the cystocele and rectocele.

Q. Okay. So if you're doing an apical repair, are you doing this thing with the small piece of mesh?

A. If I'm doing it abdominally.

Q. Okay. Is that what you usually do?

A. I do both, vaginally, abdominally.

Q. What I'm trying to figure out when you're talking to a patient that has an anterior cystocele, do you tell them typically, typically, "I'm going to do a native tissue repair with respect to the anterior prolapse, but we're also doing apical repair at the same time"?

Is that what you say typically?

A. If it's a distension cystocele, so left to right, okay, what we do when we

fix a distension cystocele, we basically just -- you have a piece of canvas across the roof, just tighten it up in the middle. All that needs is just sutures.

Q. Okay.

A. Okay.

If it has a distension and a displacement, you got to pull the top up. Otherwise you'll shorten the vagina.

Q. And the pulling the top up is what you use the mesh for?

A. Yes.

Q. Okay. And you may do that either vaginally or abdominally?

A. There is a vaginal procedure called the sacrospinous which attaches the top of the vagina to the sacrospinous ligament.

Q. And you use mesh in connection with that?

A. I use sutures or mesh.

Q. And what mention -- if you're using it either for the ASC or the sacrospinous, what function does the mesh

serve?

A. It's a suspension point so that when the vagina tries to evert, it holds it in position.

Q. Is acute or chronic pain a potential complication with a native tissue repair?

A. No.

Q. Or an apical repair of the type you described?

A. No.

Q. Is acute or chronic pain with intercourse a potential complication of a native tissue repair or the type of apical repair you perform?

A. Yes, but typically when you do native tissue repair, the reason you have pain with intercourse is because you made the vagina too tight at the opening. So it's a consequence of a mismatch between the husband's anatomy and the woman's anatomy.

Q. Okay. Because the surgeon made the vagina too small when they did the native tissue repair?

A. Yes. Or the skin just got pulled together. Sometimes it's a very easy fix, you cut the skin, you suture at the right angles, outpatient, ten minutes, it's fixed.

Q. Is vaginal scarring a potential complication of native tissue repair?

A. Yes.

Q. Is infection a potential complication with native tissue repair?

A. Very, very rarely.

Q. Well, infection is a very rare complication with Gynemesh® repair as well, true?

A. No.

Q. What is the percentage of infection with Gynemesh® repair?

A. Every woman that has an exposure has an active infection in that tissue.

Q. Urinary problems of frequency, urgency, dysuria, obstruction, retention and incontinence, is that a potential complication of a native tissue repair?

A. There's a whole list there.
Q. I thought all of them were. Is that not right?
A. Well, not all of them.
Q. Well, let's go down them.
A. Okay.
Q. Is urinary frequency a potential complication of native tissue repair?
A. No.
Q. Urgency?
A. No.
Q. Dysuria?
A. No.
Q. Retention?
A. No.
Q. Obstruction?
A. No.
Q. Incontinence?
A. Yes.
Q. Is organ or nerve damage a potential complication of native tissue repair?
A. Yes.

Q. Bleeding, is that a potential complication?
A. Yes.
Q. Wound complications?
A. Yes.
Q. Inflammation?
A. Yes.
Q. Fistula formation?
A. Yes.
Q. Pelvic floor neuromuscular pain?
A. Yes.
Q. Lower extremity pain?
A. No.
Q. Is recurrent surgery a potential risk of native tissue repair?
A. Yes.
Q. Foreign body response from sutures, is that a potential complication of native tissue repair?
A. Yes.
Q. Exposure or erosion of sutures, is that a potential complication of native tissue repair?

A. Yes.

Q. Contraction or shrinkage of tissues in connection with scarring, is that a potential risk of native tissue repair?

A. Yes, but only if the surgeon removes too much tissue.

Q. Okay. Now, well, won't you get some contraction from scarring even with a properly performed native tissue repair?

A. Not really. The vagina's different. If anything, you're going to get more relaxation, which is why there's a lower percentage rate, if it's not done correctly.

Q. Do you have an opinion as to what the percentage is of erosion or exposure with Gynemesh® PS?

A. No.

Q. Do you have an opinion as to what the percentage of recurrent prolapse is with Gynemesh® PS?

A. It's less than native tissue repair, but the number of complications and reoperations from mesh problems is much more.

Q. Okay. We'll break that out.

What is the -- you said about a 30 percent recurrence rate with native tissue repair is the generally recognized number.

What is the generally recognized figure for recurrence of prolapse with Gynemesh®?

A. A piece of Gynemesh®, right?

Q. A piece of Gynemesh®?

A. 25.

Q. 25 percent?

A. (Witness nods head.)

Q. What is it with Prolift®, which is made out of Gynemesh®?

A. 18 to 25.

Q. Then you said the complications are more, right?

A. Yes.

Q. That's what I heard in the second part of your answer.

Can you give me any percentages as the complications with native tissue repair versus the complications with Gynemesh® surgery for prolapse?

A. Would you ask the question

again?

Q. Yeah.

You said -- when I asked you what the comparative recurrence rates were, okay, you said, "Well, the recurrence rates are lower with Gynemesh® for prolapse, but there's more complications."

Okay. What I'm trying to do is figure out how much more.

A. Okay.

Q. So what would you say to that?

A. So with native tissue repair, the main issue is recurrence, which is why someone at some point thought let's do what we do in abdominal surgery and put a piece of mesh in there.

So what was the question again? The --

Q. How would you compare the risk of complications with Gynemesh® used in prolapse repair versus complications from native tissue repair?

A. So you have a slightly higher recurrence rate with native tissue. You

don't have as much contracture. You don't have scarification. You don't have a foreign body reaction. You don't have a foreign piece of mesh in there. The pain with intercourse from anterior repair only is virtually negligible. If a woman has just an anterior repair, rates of pain with intercourse from an anterior repair are virtually zero.

If you add anterior -- if you add mesh to the anterior vagina, you have a slightly higher success rate, but you increase your chance of pain with intercourse. Exposure rates, 15 percent. Maybe higher. And that's in the short term.

I don't think anyone really knows if you get out five years what really happens with the bridging fibrosis and the stress yielding that that tissue gets thin and eventually pops through and then it starts the cycle with infection and erosion and vaginal discharge.

Q. So do you have any opinion as to what percentage of women that have had a

Gynemesh® PS product put in of any kind for prolapse, what percentage of them have had long-term complications?

Do you have an opinion on that?

A. No.

Q. Okay. Do you have an opinion of the percentage of women who have had a native tissue repair have had long-term complications?

A. Very rare.

Q. Okay. And have you done any literature review to try to determine what the long-term complications are with -- over a period of years for women who have had a Gynemesh® PS product used for prolapse?

A. I have.

Q. Okay. And have you found any literature?

A. There is very little papers that talks about pieces of Gynemesh® put in anteriorly or posteriorly.

Q. You're changing my question. I said Gynemesh® product.

Okay. So have you done any

literature search to determine any product that uses Gynemesh® in prolapse repair to determine what the long-term complications are?

A. Yes.

Q. Okay. And what have you found?

A. That the use of Gynemesh® in the vagina increases a woman's chance for reoperation for complications --

Q. No, I meant what papers have you found. I asked if you had done a literature search.

A. What papers?

Q. Yeah.

What papers -- well, let me back up.

Are there any papers in your report that address the issue of long-term complications with Gynemesh® PS product, any Gynemesh® PS product?

A. No.

Q. Okay. Do you believe that the long-term complications from Gynemesh® PS cut out of a sheet are less than the

complications connected with Prolift®?

A. Yes.

Q. Okay. How much less?

A little bit? A lot?

A. A lot less.

Q. Okay. Do you have an opinion as to the percentage of erosion exposure with Gynemesh® PS? Not Prolift®, just Gynemesh® PS.

A. I'm not sure I understand the question.

Q. For Gynemesh® PS used in prolapse repair, not Prolift®, just Gynemesh® PS cut out of a sheet, do you have an opinion as to the percentage of exposures or erosions that occur with that?

A. All the information I have is the patients I see. I don't have a denominator of how many went in.

Q. So you don't have a percentage globally?

A. No.

Q. Okay. Exposures, erosions, can they sometimes be asymptomatic?

A. Yes.
Q. Can they sometimes be treated in the office?
A. No.
Q. They can't be treated through a procedure in the office?
A. Well, let me clarify.
Q. Okay.
A. You can do that. You can take the scissors to an awake woman when the second you snip it, it bleeds, but it can't be adequately treated and here's why: When you have an exposure, what that means is that you have a portion of the graft that's in the vaginal lumen. A portion of that remaining graft as it goes laterally, wherever it goes, is covered by a very thin tissue of epithelium. The epithelium is not living tissue. Even if you trim it back and you make it smooth, that implant is still in the vaginal wall. The only way, effective way -- and there's no guidance in any of the literature on how to do this or any of the internal documents I reviewed or the IFU of

how you deal with these complications. But if you're walking on a lake, at the edge of the lake it's very thick; you can stand on it. As you get towards the middle, the ice gets thin. So where it gets thin, you fall through.

As you move back towards the edge, it's better. So the only way to effectively treat these mesh issues is not in the office. It's actually cruel and unusual punishment for the woman. It's to take her to the operating room and cut that mesh back either completely or to a point that the full thickness of the fibromuscular wall of the vagina is free of mesh. That is the only way.

Q. Can some mesh exposures be treated without complete removal of the mesh?

A. Can the exposure be removed that's visible? Yes, but can it be treated? No, because of what I just explained.

Q. So you're saying any time there's a mesh exposure, almost all the mesh needs to be removed?

A. You have to cut it back.

Q. It's not what I asked. I'm just --

A. No.

Q. It doesn't have to all be removed?

A. Yes, it does.

Q. So any time you have a -- so even if you have like a 10-millimeter exposure, you should remove all of the mesh?

A. The way you're asking the question, I have to answer yes.

Q. Okay. Why am I asking it wrong?

A. Because the way I think as a surgeon is I want to fix this woman. And the way you're asking the question is you want me to do the minimal amount to get past it. So I'm honestly answering that. The treatments that have been set forth in helping these women are a problem, which is why all of these women have all these issues.

So, no, it can't -- it can't be partially removed.

Q. So if doctors, surgeons out there, if they, after surgery, three months, six months later, have a small, 10-millimeter or so exposure, you're saying that what they should do is remove all of the mesh at that time?

A. Yes, I would call that big. I think if there's a couple fibers, you can watch it. There is no evidence whatsoever to suggest that estrogen helps, but maybe if you rub it in there and you promote some blood flow or somehow, it may help with some fibers.

But once you have -- it's sort of like a fistula. When you fix a fistula, even though the fistula is 45 millimeters, the defect around it, there's probably another circumference of 3 or 4 millimeters, which is why fistulas fail when you fix them.

So if you're only removing that part that's on the thin ice, the example I used on the lake, the woman is going to have a problem because it's in the vaginal wall. So can you leave maybe a little behind? But

even when you do, it's been my experience in seeing these women that they're going to come back with pain because the edge now is no longer flat. The edge now pokes through the tissue. When the mesh is intact and it's flat, you have a sheet of human tissue over it, it's not poking her. When you cut it, it is like a sawblade poking at her because the fibers are like sutures poking through.

Q. Are you aware of any peer-reviewed literature that supports the proposition that regardless of the size of the exposure that all mesh should be removed, if there's an exposure?

A. No.

Q. Would you agree that there are many patients that have benefitted from Gynemesh® PS being used for prolapse?

A. No.

Q. Are there any?

A. No.

Q. Why do you say that?

A. It's a very biased view in the patients I see and their lives are totally

devastated from what's happened.

Q. Well, I didn't ask about the patients you saw.

Do you believe in the world are there many patients that have benefitted from Gynemesh® PS being used to treat their prolapse?

A. I do not.

Q. Okay. Do you believe there's any patients in the world that have benefitted from TVT® being used for their stress urinary incontinence?

A. Some, yes.

Q. Most, true?

A. Based on the patients that are in the -- that have been followed and based on all the data that can be transposed to the world, okay, if you take Ulmsten's data and you take the Oga position paper, the Oga paper that is cited on the back of SUFU and AUGS and you look at the grade of the reports, those patients in those studies, they're not high-grade, quality studies, but there's about 15,000 patients that are

reported in there.

So if you extrapolate all that data, okay, I would agree that 85 percent of the women are cured of their incontinence. What none of us know is what are the long-term consequences. Because when you look at that paper that's cited on the AUGS, SUFU statement position paper and you really read that paper, it actually talks about needing long-term data for mesh implants.

Q. And who is the author on that?

A. That was Oga.

Q. You don't believe there's any safe alternative for the use of mesh -- I mean, there's no safe use of mesh in the vagina for prolapse, true?

A. Not the current mesh that we have.

Q. Well, you can't identify -- that would be the better way to say it.

You can't identify a mesh that's out there on the market that you would consider to be safe for prolapse repair, true?

A. From my reading of the documents, I have learned that there is a mesh that's better than polypropylene, Pronova.

Q. My question was do you know whether it's safe or not?

A. Based on the information I have and the characteristics of the mesh, it's safer.

Q. But that wasn't my question whether there was one safer.

My question is it safe, would you use it in the vagina?

A. Yes.

Q. Okay. Why?

What's different about it?

Who makes Pronova, by the way?

A. Ethicon.

Q. What's safer about the Pronova?

A. So the fibers are completely different. When you look at certain studies --

Q. I'm going to have to withdraw and interrupt just a second.

Has Pronova been used for prolapse repair successfully in studies?

A. Hasn't been used.

Q. Okay. But you believe if it was offered to you, you would use it for prolapse repair?

A. Yes.

Q. Okay. And even though it hasn't been proven in any studies?

A. It hasn't been used -- it's been looked at biocompatibility.

Q. Okay. All right. So briefly what is it about that mesh that you believe you would use it for prolapse repair?

A. The long-term inflammation is reduced.

Q. Because?

A. It's a different chemical. It's polyvinylidene fluoride.

Q. Okay.

A. And when they -- even Ethicon themselves has done testing on it, it is a much more stable filament than polypropylene, and studies where it's been implanted and

explanted, the filament doesn't show. The filament is cracks, the polypropylene shows.

I've read documents that says that the preparation of the polypropylene filament through the stretching and the heating creates a core that cools differently than the external, which is why the external is subjected to cracking. And there's metals that are used to stabilize it and peroxidases during the inflammatory process start to degrade it. It's a vicious cycle which is why the chronic reaction occurs.

Q. Is there any peer-reviewed literature establishing Pronova as a good product for prolapse repair?

A. No.

Q. When you have patients coming to you that have had mesh and they're having some issues with them, do you always recommend an explant of the mesh?

A. Ask the question again, please?

Q. Yeah.

Did you have patients coming to you -- you said from all over -- that have

had a mesh product implanted in them, do you always recommend explanting of the mesh?

A. No.

Q. When do you not?

A. When there's nothing clinically that I think I can add by removing it.

Q. Okay. Do you ever have patients come to you who say, "I'm not having any problems or much problems, but I would still like the mesh taken out"?

A. Yes.

Q. Okay. Do you take it out under those circumstances?

A. No.

Q. Okay. I think there are some that do that, that's why I asked.

What is your charge for an explant procedure?

A. I accept insurance. Whatever the insurance pays.

Q. And how many of those do you do each year?

A. As I mentioned earlier, I've narrowed it down. In 2015, I took out 296

implants.

Q. And before that, it was another 20 percent or something above that?

A. I think I hit 400 one year, and I decreased the number.

Q. Have you ever had any nerve entrapment in any -- have you ever found any nerve entrapment as a part of your explant procedures?

A. Yes.

Q. Rarely?

A. Yes.

Q. Okay. How do you know that there's nerve entrapment as you do an explant procedure?

Is that confirmed by pathology, or what's your basis for that?

A. The TVT® sling was attached to the obturator nerve directly, and I touched the mesh to free it up and the patient's leg jumped.

Q. Was that as a result of a surgical technique problem?

A. It's a result of the IFU and

the directions that's given to the surgeon to use a large trocar.

Q. Okay. Was that the only occasion you've had a nerve entrapment problem?

A. It's been several times. I don't like giving an exact number because I don't track all of those things. What I track is how much I help patients with what I do.

Q. But that was something -- was the nerve -- in the example you gave, was the nerve entrapment, did that occur -- was that producing symptoms for the patient?

A. Yes.

Q. Okay. Now, before the Prolift®, when it's -- strike that.

Gynemesh® PS, Gynemesh® PS has bidirectional elasticity, doesn't it?

A. Yes.

Q. And it maintains that to some degree once it's put in the body, true?

A. No.

Q. Not at all?

A. The elasticity.

Q. Bidirectional elasticity to some degree remains with the Gynemesh® PS when it's put in the body?

A. Oh, let me change my answer to, yes, in the short term.

Q. Okay. How much Gynemesh® PS is used typically -- not Prolift®, just Gynemesh® PS, used for a prolapse repair?

How much is used?

A. Depends where --

Q. Anterior.

A. Anteriorly?

Depends on the woman's vagina, but let's say average of 7 centimeters by 6.

Q. Okay.

A. Maybe -- and there's longer and wider depending on the bony structure.

Q. How about posteriorly?

A. The posterior segment tends to be a little longer. 9 by 5.

Q. The meshes from other companies that use -- that are used for prolapse, do any of those have bigger pores or lighter

weight?

A. I want to make sure I understand the question.

Q. Yeah.

There's other mesh products that can be used for prolapse repair, right?

A. Yes.

Q. Have any of those had a lighter weight or bigger pores than a Gynemesh® PS?

A. Yes.

Q. Okay. Which one?

A. Coloplast is much lighter.

Q. Okay. And when did that come on the market?

A. I can't tell you the exact date. Probably in the last seven, eight years.

Q. What's its gram per meter squared?

What's its weight?

A. It's -- I think it's 27.

Q. And what is Gynemesh® PS?

A. 45.

Q. Are you familiar with any

peer-reviewed literature that is critical of the pore size or weight of Gynemesh® PS?

A. No.

Q. Have you ever written in a medical record that a patient had clinical problems resultant to particle loss or degradation?

A. No.

Q. Did you review the -- strike that.

I asked you before some questions, and I can't remember whether they were TVT®-related or not, but have you reviewed other warnings information that was given to doctors other than the IFU with respect to Gynemesh® PS products?

A. I reviewed everything that was given to me. I don't recall specifically at this time.

Q. Do you recall reviewing the surgeon's monograph with respect to the Gynemesh® PS products?

A. I don't recall.

Q. Did you read the Prolift® IFU

when you used it that one time?

A. I did.

Q. Had you read it since until you became involved in this litigation?

A. I read it again.

Q. When you became -- that's what you mean.

A. Yes.

Q. But the gap of years, you hadn't read it in between?

A. I looked at it from time to time. I read a lot of IFUs. As I mentioned earlier, I own all of the products because I have to study them on how they're designed to be able to remove them. Elevate's different than Apogee and Perigee® and Avaulta®. So I do review them from time to time.

Q. And did you say you have not served as an expert witness against any other company?

A. I'm not sure I answered that question.

Q. Okay. Have you?

I'll ask you again.

A. Yes, I have.
Q. Which against?
A. Boston Scientific.
Q. And what product?
A. Prefyx and Solyx.
Q. And what are those?
A. Those are -- one is a single-incision sling and the Prefyx --
Q. Is that like a TVT-Secur?
A. Different. It has plastic arrowheads that attach to the muscles.
Q. Okay. So which one is that, Solyx or Prefyx?
A. Sorry, the single incision.
Q. Yes.
A. Solyx.
Q. So you've testified as an expert witness against the Solyx product?
A. Yes.
Q. You said that it is -- never should have been on the market?
A. Yes.
Q. Okay. And what about Prefyx, what kind of product is that?

A. That's a sling.

Q. Okay. What kind of sling?

A. Prepubic.

Q. Okay. Different from retropubic?

A. It's in front.

Q. Okay. And what's the problem with it?

Well, let me ask you this: On both of those products, have you been critical of the instrumentation?

A. Yes.

Q. Have you been critical of the technique described in the IFU?

A. Yes.

Q. And have you been critical of the design of the material?

A. Yes.

Q. Okay. And you don't believe either one of those should have been marketed?

A. No.

Q. Okay.

A. And they're not on the market.

Q. Okay.

A. They're gone.

Q. So is there any sling product in the world that -- polypropylene sling product in the world that you believe is safe in all aspects: Instrumentation, technique, and material?

A. No.

Q. Is there any polypropylene sling product in the world that you believe is reasonably safe with respect to the material, the mesh material?

A. No.

Q. Okay. When do you do an ASC? Under what circumstances?

A. So I'll perform an ASC on a patient that is a younger woman, someone that has a shortened vagina, someone that has --

Q. These are alternatives, or they have to have all of these things?

A. No, it's either --

Q. This or that?

A. This or that.

Q. Okay.

A. Someone who has a job that requires heavy lifting. Someone that has asthma or bronchitis. Just a more durable repair. She needs a more durable repair.

Q. Was it within the standard of care up until 2012 for a surgeon to use Gynemesh® PS products in repair of prolapse?

A. Would you ask the question again?

Q. Yeah.

Was it within the standard of care, the acceptable standard of care, for a surgeon to use a Gynemesh® PS product for prolapse repair up through 2012?

A. Yes.

Q. Was it within the standard of care for doctors to use TVT® for SUI, even today?

A. Yes.

Q. Okay. Did any doctor at your hospital ever use TVT®?

A. Yes.

Q. Okay. Do some still do today?

A. I think there might be one.

Q. Okay. Did any doctors at your hospital ever use Gynemesh® PS for prolapse repair?

A. I don't think so.

MR. BALL: Okay. Why don't we take a break. I think I'm about finished here. I've got to regroup a little bit here.

(Off the record at 1:32 p.m.)

QUESTIONS BY MR. BALL:

Q. Doctor, would an experienced surgeon before 2005 performing prolapse surgery with Gynemesh® PS know that pain with intercourse was a possible complication?

A. Yes.

Q. Would an experienced surgeon before 2010 using Gynemesh® PS for prolapse know that vaginal scarring was a possible complication?

A. Yes.

Q. Would they know that infection was a possible complication?

A. Yes.

Q. Would they know that urinary

frequency, urgency, dysuria, retention, obstruction and incontinence were possible complications?

A. If we could break that question up again.

Q. Yeah.

Would an experienced surgeon before 2010 know that urinary frequency would be a possible complication after prolapse surgery with Gynemesh® PS?

A. No.

Q. What about urgency?

A. No.

Q. What about dysuria?

A. No.

Q. What about retention?

A. No.

Q. So is retention a recognized problem with Gynemesh® PS used for prolapse surgery?

A. Depends on how tight you make it.

Q. Is it a potential complication?

A. Yes.

Q. And that wouldn't have been known as a possible complication before 2010?
A. No.
Q. Why do you say that?
A. I don't think anyone knew exactly what would happen when you put mesh in there.
Q. Was incontinence a potential complication?
A. Yes.
Q. That was known before 2010?
A. Yes.
Q. Okay. Organ nerve damage, was that a potential complication that was known to experienced surgeons using Gynemesh® PS before 2010?
A. Yes.
But it's a different kind of nerve damage than -- they would know about it because they have to open the vaginal wall up.
What they didn't know was the consequence that would happen, you know, they're cutting the vagina, they're opening

it up and we talk about nerve damage, did they know about it.

So, yes, they would know about it because they're doing surgery. But what they wouldn't know about is the fact that they're going to put an implant in her that's then going to constrict and change everything.

Q. Would an experienced surgeon before 2010 using Gynemesh® -- in and before 2010 using Gynemesh® PS for prolapse know that there was a potential of contraction?

A. No.

Q. Would they know that there was a potential of scar formation?

A. Not the kind of scar we're talking about.

Q. I'm not talking about degrees.

Would they know that there would be some degree of contraction from scarring with the use of Gynemesh® PS, would an experienced surgeon know that before 2010?

A. I'm not sure I know how to answer the question. Because the way I'm

thinking about it as a surgeon is I'm going to get scarring from just doing surgery, and I think I answered, yes, that there is scarring from doing that.

But if you're asking the question is the scarring the same when putting in the mesh, then the answer is no.

Q. No, that's not what I'm asking.

A. Okay.

Q. They know they're going to create a scar by putting in mesh, right?

A. They know they're going to create a scar by doing surgery.

Q. And they know that they're going to create -- well, won't there be scarring connected with the implantation of the mesh, right?

A. Yes.

Q. And wouldn't every experienced surgeon before 2010 know that there will be some contraction connected with the scarring of the mesh surgery?

A. No. I didn't know. I didn't know.

Q. Before 2010, would an experienced surgeon -- so you're saying at no time versus before 2010 would an experienced surgeon know that there would be the potential for contraction connected with mesh surgery?

A. I'm answering that question honestly on what I knew. I don't know what other people knew so I'm answering that question based on what I knew. I was surprised the first time that I had a patient that had a contraction like that.

Q. And that was 2010, after 2010?

A. I'm not sure exactly when, but around that time frame. When the literature started talking about contraction and mesh exposure and et cetera, it all made sense.

Q. Would the average surgeon in 2010 and before know that there was a potential of erosion or exposure from mesh, from Gynemesh®, used in prolapse?

A. Yes.

Q. And would the average surgeon in 2010 or before know that there was a

potential for another surgery after the use of the mesh for prolapse?

A. Probably not.

Q. Would they know there was the possibility that some mesh might have to be removed?

A. I think what they -- no, what they knew is that they were going to apply silver nitrate in the office and put some estrogen on it and that would take care of it, and it didn't.

Q. So you don't think the average surgeon knew that a possible complication of using Gynemesh® for prolapse was that there might need to be surgery to remove some of the mesh?

A. No.

Q. Did the average surgeon in 2010 or before know that if they used Gynemesh® for prolapse there might be a recurrent prolapse?

A. No.

Q. They thought it was going to be 100 percent successful?

A. Oh, they thought it was going to be fantastic.

Q. 100 percent?

A. Close to it. 100 percent doesn't exist in clinical medicine, but --

Q. Well, I asked did they know that a potential complication was that there would be a recurrent prolapse?

A. I don't think they did, no.

Q. Okay. Did the average surgeon in 2010 or before know that the -- there was a potential for a long-term foreign body response from the mesh?

A. Absolutely not.

Q. Did the average surgeon in 2010 or before who implanted TVT® know that there was a potential for pain with intercourse?

A. No.

Q. Did that person know that there was the potential for vaginal scarring?

A. No.

Q. The potential for erosion or exposure?

A. Probably, yes.

Q. The potential for a chronic foreign body response?

A. No.

Q. The potential for a failure of the procedure to cure the SUI?

A. Yes.

Q. The potential for an additional surgery?

A. Yes.

Q. The potential for some of the mesh to be removed?

A. No.

Q. And the potential of contraction of the TVT®?

A. No.

Q. When do you think that doctors became aware of the problems that you've described for us today?

When did the medical community become aware of the problems that you've described about TVT® and Gynemesh®?

A. After 2011.

Q. Okay. And what happened in 2011?

A. Well, there was the initial FDA announcement that that some of these things might be rare, and then in 2011 when it wasn't rare, and it all just kind of blew up.

Q. You said there was the initial announcement.

When was that?

A. I believe it was 2008.

Q. Right.

So wasn't there general knowledge in the medical community in 2008 of these problems that I just listed?

A. To some degree, but it wasn't really an awareness. I didn't -- I'm answering the question honestly based on what I knew because that's what I know. I'm not sure what other people knew. Maybe there were some that are more alert and smarter than me out there, but I didn't know the extent that all of these problems would exist until after 2011 and especially 2012.

I would see patients, and I didn't think it was the mesh either. I didn't really know what to tell them until

all of these announcements happened.

Q. Your referrals for explants, where do they come from?

A. They are global.

Q. Let me ask you this, a simpler question.

Do any of your referrals for explants come from lawyers, where the patients were referred by lawyers to you?

A. So the short answer is yes because these patients ask their lawyers where can I get help. So at least in St. Louis I am one of the people that can fix this. My referrals come from other doctors, other patients, other surgeons, that put in mesh, urologists, gynecologists, internal medicine doctors.

Q. And lawyers?

A. Yeah.

Q. Okay. Do you know what percentage of your referral practice comes from people involved in litigation?

A. It's a very small percentage. 2 percent.

Q. Do you ask every one of your explant patients whether they're involved in a lawsuit?

A. I do not.

Q. So how do you have any basis for knowing that?

A. They fill out a little piece of paper.

Q. About referral?

A. About referral, and it says "Attorney."

Q. Okay. So my question -- I appreciate that. My question is a little bit different.

I'm not talking about people who are directly referred. I'm asking about what percentage of your patients are involved in a lawsuit.

A. I don't know. I don't ask. It's really none of my business.

Q. And you don't ask?

A. I don't ask.

Q. Are you familiar with any medical principle that complaints of pain can

be affected by secondary gain?

A. I'm sure there are, which is why when patients show up, if I can't find more than one reason -- and I just submitted an abstract to the AUGS; it's not accepted yet -- very few patients present with a single symptom that I've operated on. They usually have pain, erosion, failure of the device.

So it's -- I'm not -- I don't know if you're implying, maybe you're not, but I'm going to answer the question. I'm not looking to remove the mesh when there's no problem. I put it in. So if it's working fine, and I think it's in the best interests of the patient to leave it alone, I leave it alone.

But there's a large number of patients that truly have problems that don't know where to get help. There was a paper by I think Shakain and Posen that said many years ago that there ought to be referral centers.

Q. Shakitan and Kosan?

A. Is that how you say his name?

Okay. There's a bunch of papers that I reviewed, and I can't say their names. They're not in my reports, but I don't know what's on the thumb drive. I think I got 52 discs or something like that. So that there ought to be places where these women can have help.

So that, to me, was the first time that someone recognized that these women have legitimate problems, and there is nothing anywhere to help guide care for them.

Q. Tell me about the paper you submitted to AUGS.

A. It's an abstract.

Q. An abstract.

A. An abstract.

Q. And was it based on a study, or what's it about?

A. All it's doing so far -- I think it -- after going through this and being deposed, I think I will write it up. I wasn't planning on it. But all it was was looking at how many of these issues are

slings and how many are prolapse kits. That's all it really was looking at, but I'm going to reconsider that.

So the vast majority are slings.

Q. The vast -- and you told us that earlier in the deposition.

A. Okay.

Q. The vast majority of your explant procedures are slings?

A. Yes, sir.

Q. Of various manufacturers?

A. Yes.

And it's not mentioned who they are in the paper.

Q. And you don't know enough about market share and everything to determine whether the TVT® is overrepresented in your practice or not?

A. No, but I'm going to see if I can learn.

Q. Would you say that a warning is adequate if it gives a doctor sufficient information to counsel patients and make a

surgical decision?

A. Would you repeat that?

Q. Yeah.

Would you say a warning is adequate if it gives the doctor sufficient information to counsel patients and make a surgical decision?

A. If it gives adequate information?

Q. No, gives sufficient information is what I meant to say.

You said in here sometimes the warnings are inadequate?

A. Yes.

Q. You've said that. So I'm trying to get your definition of what inadequate is. Maybe I'll just ask that.

What's your definition of an adequate warning?

A. Percentages, how often does it happen, what's the severity.

Q. Of complications?

A. Yes, how is it addressed.

Q. Are you aware of any warnings

related to any kind of vaginal surgery from any manufacturer that gives percentages of complications?

A. Unfortunately, none do.

Q. Okay. So these photographs that are in your Gynemesh® report, which is Exhibit 3, what is the significance of those photographs?

They're at page 7, et cetera. 7 and 8.

A. So it shows the bunching, the rolling, the cording, the excessive scarification of the mesh once it's placed.

It doesn't --

Q. So let's take the photograph on page 8.

Tell me what that's showing, photographs.

A. I have page 7, want me to go to page 8?

Q. Yeah.

A. So it's showing a section of Gynemesh® that's been explanted. It's been cut in the middle and where the surgeon cut

it in a square, it has folded and corded near the lateral edges.

Q. Okay. And maybe we will use Jim's color ones.

Show me what you're talking about.

A. See how it's folded and rolled right there? Are we looking at the right one?

Q. Yeah. Well, I'm not seeing any folding.

So that's the mesh folding and rolling on the top picture on page 8?

A. Yes. And it can't been seen easily because it's encased in scar tissue and tissue. It's not a single flat layer.

Q. I can't tell that, but if I'm assuming --

A. Compare it to the picture below it.

Q. Okay. Which is what?

A. It's another -- it's the piece of Gynemesh® from the above picture in closer magnification. You see how it's nice and

flat and the edge here is rolled?

Q. I'm not being difficult. I don't see it, but I wanted to hear what you had to say about it so I've heard that.

I appreciate it.

A. Okay.

Q. You say on page 10 --

A. If I could interrupt for a second, a better page to represent the folding is on page 7.

Q. Okay.

A. On this one, maybe you can see it a little bit better, it's a lot thicker. See, it's thicker?

Can you see the edges?

Q. I see it's thicker. I guess that just meant more tissue came with it.

A. No. My technique is such that it scrapes it off and it's folded.

I'm sure I have the picture laterally head-on.

Q. So what you're saying in all of these photographs what we're seeing is almost totally mesh, not tissue?

A. Yes.

Q. Okay. That might have been my misunderstanding.

A. Yes.

Q. So if they're thicker, if the piece is thicker in the photograph, it's thicker because the mesh has rolled over is what you're saying; not thicker because it happens to have more tissue connected with it?

A. Correct. If I did that, I would be removing the woman's rectum and bladder.

Q. Go to page 10 of your Gynemesh® report, it says in the middle of the page, "The Gynemesh® PS contains pore sizes much smaller than the necessary 1 millimeter."

A. Yes.

Q. This gets to the variable pore size you were talking about before?

A. Yes.

Q. Do you know what percentage of them are smaller than 1 millimeter, and what percentage are larger?

A. I didn't do a calculation on the percentage, no.

Q. How would Ethicon be able to determine the percentage of complications?

You said a warning to be adequate needed to give the percentage of the potential complications such as erosion and nerve damage and --

A. Yes.

Q. -- contraction, et cetera.

How would Ethicon determine the percentages to put in an IFU?

A. What they would have had to do when all of this -- when these products started is very similar to what's given to a patient that has a pacemaker, a card. Each of those cards is registered with the company so the company knows how many implants went in. That patient carries that card and if there's a complication, the patient calls a number to report these complications and then the patient is seen by a doctor to confirm that.

Q. Well, that process would have

taken years in order to get reliable percentages of complications, true?

A. Yes, but the company should have done a project like that prior to releasing it to the average surgeon.

Q. So how many patients would have had to have Prolift® put in at the clinical trial stage before the product went on the market in order to get reliable percentages of complications in your view?

A. 500.

Q. Other than pacemakers, do you know of any other product that used the kind of procedure you just described?

A. Yes. I believe you mentioned your daughter works in the ICU. So when someone comes in with a neurovascular injury and needs a coil, those patients get a little card that lets them know that they have coils in, et cetera, stents, filters.

Q. Is the Gynemesh® PS any more stiff and inflexible than other kinds of meshes used for prolapse?

A. It's less stiff than some, and

more stiff than others.

Q. But I think your view is they're all too stiff and inflexible?

A. Yes.

Q. Okay. Now, back to our report on -- the clinical reports at pages 21 and 22, those are footnoted at footnotes 34, kind of like through 30 -- through 39 of your report, right?

A. Yes.

Q. Do you believe that you gave a fair and balanced representation of the findings of those reports?

A. I do.

Q. Okay. Now, did those reports have conclusions in them?

A. Some did, yes.

Q. Okay. Did you cite the conclusions in your report?

A. I didn't cite the exact conclusion. What I do is I review everything that's available, and I abstract the information and --

Q. So did the people that prepared

those reports -- you've written in here that the study demonstrated that the mesh was not an effective prolapse treatment and presented unreasonable risks?

A. Yes.

Q. Was that the conclusion of the study?

A. On the conclusion by Karram, Maher on posterior vaginal wall prolapse, absolutely.

Q. No, I'm saying the conclusion of the study that's referenced at footnote 34.

A. So I was looking at the wrong one. So footnote 34 --

Q. Footnote 34 is the clinical study report.

A. Yes.

Q. And you cite data from the clinical study report, and you say your conclusion was that the mesh was not effective prolapse treatment and presented unreasonable risks.

Did the people who did this

study reach that conclusion?

A. Yes.

Q. Okay. They reached that same conclusion?

A. Yes.

There were serious adverse events. They had to distinguish between transvaginal mesh and what was Prolift®. So they didn't even met their success rate. Even though they had a success rate of 20 percent, they were, I believe, 18.5, they were really close to not being as successful as they wanted.

Q. Well, you quoted a number of pieces of data in here.

Why did you not quote the specific conclusion from the people that did the study?

A. I thought I summarized it to the best of my ability everything that was available to me. There's so many reports, so many papers --

Q. I'm talking about these reports that you quoted specifically.

Why did you not quote the conclusion of the report?

You quoted the data, but you didn't quote the conclusion.

Why is that?

A. At the time I thought that was the most important piece of information that I placed in the report.

Q. When you're giving your opinions as to whether the IFU adequately -- for the Gynemesh® PS and TVT® provides an adequate warning of the risks and complications, are you basing that on your own opinions and experience?

A. I'm basing it on the totality of everything that was known from the internal documents at Ethicon, all the material that was available to me, and knowing what's in the IFU, knowing what the company knew that they didn't include and my own experience.

Q. Is there any objective standard that you are applying in determining whether the warnings were adequate?

A. Yes.

Q. What's the objective standard?

A. If, for example, it's mentioned repeatedly in the internal documents for a very long time that there's a problem with the product, and they're not including it, that's not a fair representation of truthfulness of what's wrong with the product or not.

Q. What's the objective standard you're applying in reaching that conclusion?

A. I'm not sure I understand the question then.

Q. Well, then sometimes they're like FDA regulations, there's industry standards.

Is there any kind of standard you can point to and say, "This is the standard that should have been applied to the warning," and they didn't meet it?

A. Yeah, Ethicon's own -- where it says our credo is to take care of our doctors, our nurses and our patients. They had an obligation if they knew that these

meshes had biodegradable components and they knew it, and they have a credo that says we're going to take care of our doctors, our nurses and our patients, and they put it in, I think that's a very objective way of saying they knew about it, and they didn't disclose it.

Q. You do not rely upon internal company documents in making decisions for your patients, true?

A. I don't get -- no, I don't have internal document access.

Q. Right.

And other than the Boston Scientific products you've mentioned, other than the two Ethicon products here, are there any other products you've been engaged upon to testify about?

A. I've been deposed as an expert on those two products we've talked about.

Q. Plus the two today?

A. Yes.

Q. And that's it?

A. Yes.

Q. Okay. Now, all of the materials that you reviewed in this matter were sent to you by the lawyers for the plaintiffs?

A. Yes.

Q. Okay.

A. 52 discs.

MR. BALL: And they're all in the CD, all 52 of them; is that right?

MR. MATTHEWS: It's what my paralegal says. I promise -- I have not looked at it to verify that.

QUESTIONS BY MR. BALL:

Q. Did you ask the lawyers whether there were any other documents or depositions other than what they gave you?

A. I don't think I did.

Q. And did you do any research of your own into the medical literature independent from the medical papers they gave you?

A. Yes, I did.

Q. And how did you do that?

A. I subscribe to -- I'm a member

of the International Gynecologists Association, so I went on the website and I put in keywords searching the Blue Journal, International Journal of Urogynecology. I did the same for the American Journal of OB/GYN. I did the same for Obstetrics and Gynecology. And then I asked my librarian to do a search, and I asked her to do a search for "Gynemesh®" and "TVT®."

Q. Okay. Did you come up with any papers that were different or additional to what the lawyers had given you?

A. There were some different ones, but when I looked at them, I didn't really think that they added -- either had bias, they were either employees of Ethicon, or they were -- the studies were funded by Ethicon or there were weaknesses in the methodology so I didn't use them.

Q. So your opinion that there is no reasonably safe mesh product for SUI, would you agree that there's a large body of published peer-reviewed literature that runs counter to that opinion?

A. I do.

Q. Okay.

A. But here's what else I know: Everyone understands, clinicians, doctors, companies, that we need lightweight, macroporous mesh. And they've done wonders to try to conduct research on that. There is a paper by Mowali that even says that the current Gynemesh® PS when placed in rhesus monkeys not only doesn't help, it's detrimental to the vagina of a rhesus monkey, which is probably the best paper out there because it's not a pig, it's not a cow, it's not skid. It's the closest to the human vaginal tissue as possible. Not only does it not help, it's detrimental. Every aspect of healing is impaired by Gynemesh® PS.

So everyone knows that we need lighter weight meshes, and yet every single company, including Ethicon, continues to use a sling that's 100 grams per meter squared.

MR. BALL: Okay. I'll just have to move to strike everything after the words "I do."

QUESTIONS BY MR. BALL:

Q. Would you agree that the general scientific consensus is not in line with your opinion that there is no reasonably safe polypropylene sling for use with SUI?

A. No.

Q. That's not the general consensus, true?

A. I don't think it's a general consensus.

Q. Okay. Thank you.

Can you tell me -- if you saw studies and decided not cite them in your reports, can you tell me what criteria you used to what was cited in the report and what wasn't?

A. Number of patients, follow-up, if the report was done by someone that I identified in my reading as an employee of Ethicon or if the study was funded by Ethicon. Those have a lot of bias to them.

Q. Well, are you saying that studies funded by a company in which companies participate are automatically not

reliable?

A. They have bias to them.

Q. I didn't ask that.

Are they automatically not reliable?

A. Sometimes, yes.

Q. All of them?

A. I wouldn't say all of them.

Q. There's a lot of good scientific data that's produced by studies funded by companies, true?

A. Some.

Q. Would you agree that your opinion that there is no safe TVT® -- strike that.

Would you agree that your opinion that TVT® was so unsafe it never should have been on the market is not generally accepted in the scientific medical community? You agree with that?

A. Yes.

Q. Okay. So did you automatically not consider any study that had any funding from Ethicon?

A. I considered it.

Q. Did you automatically not cite in your report any study if it had funding from Ethicon?

A. No.

Q. You didn't cite it?

A. No, and that's not the question I'm answering.

Q. I am sorry.

You still would include it in your report although it might have been funded by Ethicon?

A. If I thought it had merit, I would have.

Q. Okay. And so you're saying any of the -- you remember we went through some long-term studies with respect to both Gynemesh® PS products and TVT®.

Do you remember that?

A. Yes.

Q. And you didn't cite any of those in your report?

A. So one of them I don't recognize --

Q. Let me finish the question.
A. Okay.
Q. You did not cite any studies giving long-term results on either Gynemesh® PS products or TVT®, true?
A. Correct.
Q. Okay. And are you saying that none of those were reliable studies?
A. When I assess them, I did not think that they had the merit that I wanted to use them in my report.
Q. And what was your basis for that?
What was non-meritorious about them?
A. I can't remember the specifics of each report, but it had to do with either follow-up, for example, the Nilsson 17-year study. I mean, I could do the calculations, but the percentages are off, and half those patients were lost to follow-up. So you can't know whether the other half are doing well or not doing well.
Q. We talked about that one.

What about any other studies?

I want to know other studies that you say you considered that were long-term follow-up, a year or more, for either Gynemesh® or TVT®, and you disregarded -- and you decided not to include them in your report.

A. There's thousands of papers.

Q. That were long term?

A. There's thousands of papers overall, and I looked at everything that I had available to me, and I put it in my report.

Q. If you thought it was -- I know that.

You didn't put -- you looked at what you had available to you. You made a decision about what to put in your report. What I'm trying to explore is how you made that decision, and I guess what I'm hearing is that if it isn't in your report and -- it was a long-term study, okay, about TVT® or Gynemesh® PS products and it's not in your report, then you considered it not to be a

valid study?

A. It was not a good study, correct.

Q. Okay. And those studies were all peer-reviewed, and some of them were published in esteemed journals, true?

A. They're peer-reviewed.

Q. What do you consider to be the kind of first tier journals in your field?

A. The ones I looked at, Obstetrics and Gynecology, the American Journal of OB/GYN, International Urogynecology Journal, Journal of Urology.

Q. What about the New England Journal of Medicine?

A. Oh, yes.

Q. Any others? I just thought of that one.

A. Yeah, it's a good one.

I think I have that one in there, don't I?

Q. How about JAMA?

A. JAMA doesn't really have a lot of pelvic floor papers, but I did include

Richter's multi-center trial on Thomas that was published in the New England Journal.

Q. When you do an explant, does your operative report record what specific product it was?

A. No.

Q. Okay. It doesn't say TVT® versus Prolift® or something else?

A. My reports are very bland. They don't point fault at the surgeon or the company, but based on some of the questions that you've asked me today, I think I may change my op reports. I don't put in there where the company is from, how much I removed. My goal in my operative report is to take care of the patient.

Q. Do you record in your report whether it's mechanical-cut mesh or laser-cut mesh?

A. I do not, but I have the implant --

Q. Don't feel obligated to change any of your practices based on my questions.

A. Oh, I'm absolutely going to.

There's an education to these questions sometimes. So what I've tried not to do is throw companies or patients under the bus or doctors in the -- I didn't mean patients -- doctors or companies under the bus in my op notes. They're very bland. This is what I did; this is what I got out. The pathology report documents what I removed. I have the implant log, I can go back and look it up, but I will add more information to my op notes.

Q. Is chronic inflammation more in the area of pathology than it is your area?

A. Chronic inflammation is a pathologic diagnosis, but it's manifested with clinical symptoms.

Q. You can have a chronic foreign body reaction and not have any clinical symptoms, true?

A. That's true.

Q. Okay. In fact, it's not at all uncommon if people have a foreign body put in their body permanently, then they often have a permanent foreign body reaction, true?

A. No.
Q. Of some degree?
A. Maybe of some degree, but not of a large degree.
Q. Right. That was my point.
When you have a foreign body put in your body, you often -- the body often has a chronic foreign body reaction, but that may or may not produce symptoms, true?
A. Yes.
Q. Okay.
A. In the case of polypropylene with the fibrillations and the cracking, it continues to perpetuate the chronic inflammatory response.
Q. Now, are you aware of any paper published, peer-reviewed paper, that says that, that polypropylene in the body produces a long-term foreign body reaction that produces long-term inflammation?
A. Yes.
Q. Okay. What paper is that?
A. Mary, 1998. She did it. She placed polypropylene suture in mongrel dogs.

Q. What's the author's name?
A. Last name is Mary, M-a-r-y.
Q. Are you aware of any paper that related to either TVT® or Gynemesh® PS or any other type of sling or prolapse product that says there's a chronic foreign body reaction that produces chronic, long-term inflammation?
A. Yes, Clavé paper.
Q. Anything else?
A. Not that I think of at this time.
Q. Is the Clavé paper referenced in your report?
A. I think it is.
Q. Can you just -- let's just make that the last thing we do.
Can you find your reference to the Clavé paper, please, in your report?
Here it is. I don't believe it's -- based on my review, I don't believe it's in the Gynemesh® PS report.
Well, I don't see it.
Do you see it?

A. How could I forget to put that in there?

Q. Let's just get a final answer, and I'll conclude the deposition.

MR. MATTHEWS: I've got a couple questions.

QUESTIONS BY MR. BALL:

Q. Okay. Would you agree that the Clavé paper is not cited in either of your reports in this case?

A. I would have to agree with you.

MR. BALL: I have reached my time limit and, therefore, I have no further questions, subject to whatever gets brought up now by Mr. Matthews.

CROSS EXAMINATION

QUESTIONS BY MR. MATTHEWS:

Q. Dr. Veronikis, is the preparation of the Rule 26 report different from a paper that you would write for a peer-reviewed medical journal?

A. The process?

Q. Yes.

A. Well, the process is different,

but the methodology is similar.

Q. Explain what you mean.

A. Well, you go through the process of looking at papers and looking at documents. What's different is that with the Rule 26 report, I have corporate documents and depositions and et cetera that you don't normally have when you write a scientific paper.

On a scientific paper, you also have research that you're conducting and considering, but the actual methodology of, you know, coming to a conclusion is the same; you take all of the data that's provided, and you weigh in what you have at hand, and you come up with a decision.

Q. When you're doing a Rule 26 report, would I be correct that you're giving your professional opinion?

A. Yes, it's my professional opinion.

MR. MATTHEWS: I don't have another question, but I see Clavé on footnote 29 on the TVT®.

MR. BALL: Well, let's look at that.

MR. MATTHEWS: It's actually referenced in an Ethicon document that's cited in footnote 29. So it's on page -- about the middle of page 21.

REDIRECT EXAMINATION.

QUESTIONS BY MR. BALL:

Q. So just so we're clear, you don't cite the Clavé paper or discuss the Clavé paper in the body of the report, true?

A. True.

Q. Okay.

A. But I did look at that paper.

MR. BALL: That's all the questions we have. Our time is up so.

MR. MATTHEWS: We'll get a rough, and send me everything they get.

(Deposition concluded at 2:28 p.m.)

- - - - - - -

CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Merit Reporter, Certified Realtime Reporter and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, Dionysios K. Veronikis, M.D. was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

CARRIE A. CAMPBELL,
NCRA Registered Merit Reporter
Certified Realtime Reporter
California Certified Shorthand Reporter #13921
Missouri Certified Court Reporter #859
Illinois Certified Shorthand Reporter #084-004229
Texas Certified Shorthand Reporter #9328
Notary Public

Dated: May 4, 2016